IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY ASSESSMENT OF ENZYME FERMENTATION PROCESSES

AT

Miles Laboratories, Inc.
Elkhart, Indiana

REPORT WRITTEN BY:
John W. Sheehy
Kenneth F. Martinez

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
Division of Physical Sciences and Engineering
Engineering Control Technology Branch
4676 Columbia Parkway
Cincinnati, Ohio 45226

PLANT SURVEYED.	Miles Laboratories, Inc. 1127 Myrtle Elkhart, Indiana 46515
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SURVEY DATE:	November 18-22, 1985
SURVEY CONDUCTED BY:	Kenneth F. Martinez John W. Sheehy Dennis M. O'Brien Michael G. Gressel James H. Jones Phillip A. Froehlich Karen L. Lenihan
EMPLOYER REPRESENTATIVES CONTACTED:	Gary Blair, Director of Quality Assurance Tom Bauckham, Corporate Industrial Hygienist Joseph Brady, Consultant Paul Kelley, Plant Manager Nevin Meyer, Executive Vice President of Biotechnology Division John Polhemus, Corporate Safety and Health Manager Kurt Poulos, Quality Control Supervisor Ed Hickman, Plant Engineer Jeff Leech, Production Supervisor Ron Heinrichs, Laboratory Supervisor
EMPLOYEE REPRESENTATIVES CONTACTED:	United Steelworkers of America, Local 12273
ANALYTICAL WORK PERFORMED BY:	Lucy B. Cusick, CDC, CID, HIP Barbara A. MacKenzie, NIOSH, DBBS, ISB

I. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) is the primary Federal agency engaged in occupational safety and health research. Located in the Department of Health and Human Services (formerly DHEW), it was established by the Occupational Safety and Health Act of 1970. This legislation mandated NIOSH to conduct a number of research and education programs separate from the standard setting and enforcement functions carried out by the Occupational Safety and Health Administration (OSHA) in the Department of Labor. An important area of NIOSH research deals with methods for controlling occupational exposure to potential chemical and physical hazards. The Engineering Control Technology Branch (ECTB) of the Division of Physical Sciences and Engineering has been given the lead within NIOSH to study the engineering aspects of health hazard prevention and control.

Since 1976, ECTB has conducted a number of assessments of health hazard control technology on the basis of industry, common industrial process, or specific control techniques. Examples of these completed studies include; abrasive blasting,[1] the plastics and resins industry,[2] foundry operations,[3] spray painting and coating,[4] and coke oven emissions.[5] The objective of each of these studies has been to document and evaluate effective control techniques for potential health hazards in the industry or process of interest, and to create a more general awareness of the need for or availability of an effective system of hazard control measures.

These studies involve a number of steps or phases. Initially, a series of walk-through surveys are conducted to select plants or processes with effective and potentially transferable control concepts or techniques. Next, in-depth surveys are conducted to determine both the control parameters and the effectiveness of these controls. The reports from these in-depth surveys are then used as a basis for preparing technical reports and journal articles on effective hazard control measures. Ultimately, the information from these research activities builds the data base of publicly available information on hazard control techniques for use by health professionals who are responsible for preventing occupational illness and injury.

Background for this Study

NIOSH's research responsibility extends to both existing and emerging technologies which may affect worker health and safety. The attempt to examine new technologies for potential occupational hazards focuses on those technologies which have high growth potentials or for which exposures to particular agents have not been fully characterized. In past research activities, NIOSH has been instrumental in the development of recommendations for safeguarding the workers health from exposure to occupational hazards. Implementation of safeguards and protective engineering controls early in the growth of an industry will minimize occupational health problems and avoid expensive retrofitting of production systems.

NIOSH is currently interested in evaluating the potential hazards and their control for applications of biotechnology and recombinant DNA (rDNA). ECTB's involvement in this NIOSH evaluation is to assess the control technology being

employed to minimize the potential for occupational health hazards in the enzyme fermentation industry. The results of this control technology assessment will be used to develop an informational database that could be extrapolated to other fermentation product technologies. Previous NIOSH research into biotechnology includes a study of six companies employing rDNA techniques in their research activities or their process operations. This earlier study, conducted by the Division of Surveillance, Hazard Evaluation, and Field Studies, was published in a NIOSH report and a journal article.[6,7]

The ECTB study is focused on conventional enzyme fermentation process operations. Several factors contributed to the final decision to focus on this industry. First, the products manufactured in the overall fermentation industry, although dissimilar entities, are produced with a somewhat standardized process technology. Product recovery operations may vary with the product properties, source microorganisms, and base solvents used, but the basic fermentation technology remains essentially the same. Second, the diversity of the fermentation industry would require different environmental air sampling and analytical methodologies for each product and source microorganism studied. Narrowing the field of investigation satisfied the need to limit the "products" studied in order to minimize sampling and analytical methods development requirements. Third, there was a good probability of finding well controlled processes in the enzyme industry. Last, there existed limited resources (including manpower and finances) with which to conduct this study and time constraints on its completion. Initial studies of various enzyme production plants identified several well controlled processes. Additional studies may evaluate other areas of the fermentation industry including antibiotic, hormone, and steroid production.

This control technology assessment of enzyme fermentation processes attempted to identify effective controls applicable to processes involving microorganisms, processing chemicals, and biologically active products or intermediates. The documentation of effective controls and recommendations to minimize exposure in the enzyme fermentation industry are among the primary objectives of this assessment. Recognizing that the enzyme industry only represents a small segment of the biotechnology industry, the collected data and subsequent evaluation will help to establish a baseline of information on the equipment (and related safety and health programs and practices) currently used in enzyme fermentation operations. This baseline of information will be available for transfer to other fermentation technologies, either those involved with rDNA technology or those utilizing conventional technology.

Plant Selection

Selection of plants for inclusion in this study of enzyme fermentation processes as in-depth surveys was based on a number of criteria. First, the plant (or parent company) should be a major manufacturer of industrial enzymes or have extensive experience related to fermentation technology. Second, the process operations should be technically current to insure the transferability of the survey results to other fermentation industries -- including those recombinant DNA companies scaling up operations to commercial production capacity. Third, the plants should exhibit an expressed concern for the safety and health of the workers. This would involve adherence to any or all

of the aspects of control technology to protect the worker including engineering controls, personal protective equipment, work practices, and industrial hygiene monitoring.

Miles Laboratories, Inc. met all three of the in-depth survey selection criteria requirements. Miles is a major manufacturer of industrial enzymes used in the processing of dairy and food products. Miles, as a subsidiary of Bayer A/G of Germany, has available a broad base of experience related to enzyme fermentation technology, in addition antibiotic production. Miles has demonstrated a strong interest in worker safety and health by applying control measures to limit the potential exposure to hazards, employing an environmental monitoring program, requiring the use of protective equipment for certain tasks, and other such methods.

The in-depth survey of Miles was conducted on November 18-22, 1985, to evaluate the controls and containment capabilities of their carbohydrase enzyme manufacturing process. This report documents the information pertinent to that evaluation.

II. PLANT AND PROCESS DESCRIPTION

Plant Description:
The Miles enzyme operation is contained in the larger Miles Laboratories, Inc. plant complex in Elkhart, Indiana. Miles has been producing an α-amylase enzyme in the Elkhart facility since March 1982. The parent company, based out of Germany, is Bayer A/G.

Enzyme production is a 4 shift operation maintained 7 days per week, 24 hours per day. The enzyme plant employs less than 100 workers including production, maintenance, and laboratory workers. The hourly workers are represented by the United Steelworkers of America, Local 12273.

The laboratory, located in the enzyme plant near the production process, is used for both quality control, seed culture production, and process monitoring.

Process Description:
Miles produces the industrial enzymes α-amylase and glucoamylase. Aspergillus niger, a eucaryotic fungus, is used for the production of glucoamylase, and Bacillus licheniformis, a procaryotic bacterium, is used for the production of α-amylase. Both strains of microorganisms are non-pathogens.

The manufacture of the industrial enzymes is accomplished using a six step process flow: raw materials - medium preparation; laboratory - microbial preparation; inoculation - microbial growth; fermentation - product biosynthesis; process recovery - product extraction; and final product packaging. All process steps of the enzyme operation are executed in the same plant building. The process flow follows a "horseshoe" pattern through the building -- raw materials entering on one side of the building and the final, packaged product exiting on the same side, adjacent to the raw materials.

The raw material specifications used in the nutrient preparation process step are tightly controlled to prevent contaminants that would inhibit organism growth or enzyme production. Requirements for the nutrient medium include: water; carbon from carbohydrate sources; nitrogen from proteins and amino acids; minerals; and a buffer system. The raw materials are deposited into individual hoppers to be subsequently mixed with the remaining required nutrients in a batching tank. This mixture is sterilized and added to the deep-tank reactor vessels, the seed and fermentor tanks, during the fermentation process step.

The laboratory and inoculation process steps are where initial development, preparation, growth, and maintenance of the selected microorganism cultures are accomplished before being used for large-scale fermentation. All pertinent microbiological operations within the laboratory are conducted using sterile equipment with aseptic transfer to ensure pure, uncontaminated culture mediums. The selected culture is grown (from stock cultures and propagated in shaker flasks), harvested, subdivided, and then stored at the appropriate conditions to maintain its viability and purity. Microbial cultures are transferred manually and aseptically inoculated, maintaining pure cultures, into the seed tank for the first segment of the fermentation process step. The laboratory is not only used for seed preparation but also in-house quality control work.

Miles utilizes a two-phase operation in their large-scale fermentation process step -- this minimizes the possibility of contaminating large quantities of culture media and optimizes the use of expensive equipment. In the first phase, the seed fermentor containing a sterile nutrient medium is inoculated with the selected microbial culture prepared in the laboratory. The seed fermentor is designed to promote the growth of the microbial population to the level necessary for proper fermentation in the deep-tank reactor vessel. The batch mixture is aerated and mechanically agitated until the optimum level of biomass is achieved. The final contents of the seed fermentor is aseptically transferred to the large fermentor (deep-tank reactor vessel).

The second phase of the fermentation process step is where "fermentation" essentially occurs and the product of interest is biologically synthesized. A submerged, batch fermentation process is employed using a standard deep-tank reactor vessel with a top-mounted mechanical agitator and a bottom air sparger. Proper temperature conditions are maintained with cooling jackets or baffles. The fermentor tank, containing the pre-sterilized nutrient medium from the batching tank, is inoculated with the biomass broth from the seed fermentor. This new broth mixture is aerated, mechanically agitated, and allowed to ferment for biomass growth and final production of the desired enzyme. The composition of the medium used in each phase is carefully controlled to promote maximum growth of the organism and/or enzyme production.

Measurements are performed continuously during the fermentation process step to check specific parameters of the biomass broth. These measurements are predominantly computer controlled or monitored and include process parameters such as temperature, pH, nutrient addition, anti-foaming agent addition, air flow rate, back pressure in the vessel, etc. Other typical measurements monitored are the $\%CO_2$ and O_2 in the exhaust gas, the power consumption of

the agitator motor and the RPM's of the agitator. Manual samples are also extracted periodically from a port valve on the large fermentor tank for analysis in the laboratory.

In process recovery, a solid-liquid separation technique (rotary vacuum drum filter system) is utilized to extract the product enzyme from the biomass broth mixture . The enzyme slurry is pumped to the filter system (diatomaceous earth is used as a precoat) where a major portion of the suspended solids are separated from the enzyme liquid. A stellite doctor blade shaves off the filter cake and a fraction of the diatomaceous earth precoat. The solid wastes from these operations are discharged to dumpsters and transported to landfills. The enzyme liquid is then be concentrated with an evaporator. The last step in process recovery, is the final polishing or purification of the concentrated enzyme accomplished with a filter to remove unwanted bacterial contamination.

The final processing step in the Miles enzyme manufacturing process, final product packaging, is to formulate and package the concentrated enzymes. Formulation involves standardizing the activity of the liquid enzyme and adding preservatives in a mechanically agitated mixing tank. The finished enzyme product is then packaged in headpacks, drums, or a bulk tank truck.

Potential Hazards:
The generic potential for exposure to hazards in the occupational environment within the general fermentation industry is a three-fold problem. Exposure may involve potentially hazardous microorganisms (innate as-well-as genetically modified), toxic processing chemicals, and biologically active products or intermediates.

Presently, the microorganisms used by the enzyme industry, inclusive of the overall fermentation industry, for fermentation operations are non-pathogenic in nature. But future involvement with rDNA technology may produce microorganisms in need of more stringent containment requirements and equally stringent programs in occupational safety and health due to the increased health risks that they may pose to the exposed worker. Miles uses a strain of Bacillus licheniformis, a non-pathogens, for the selected enzyme manufacturing operations. Increasing attention is being focused upon the potential for immunologic response, after repeated inhalation, to a variety of organic materials including microorganisms. There are currently no reports of these effects in the enzyme industry. Cases of hypersensitivity pneumonitis have been documented in individuals exposed, in the occupational environment, to fungi, thermophilic actinomycetes, as well as animal proteins.

Diatomaceous earth (amorphous silica) is used in the concentration and purification processing step as a precoat on the drum of the rotary drum vacuum filter. Amorphous silica can affect the body if it is inhaled or if it comes in contact with the eyes. Prolonged inhalation of amorphous silica including uncalcined diatomaceous earth may produce x-ray changes in the lungs without disability. The current OSHA standard for amorphous silica is the quotient of 80 mg/m^3 divided by the percent silica present. The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a maximum exposure of 10 mg/m^3 over an eight hour work shift.[8]

Acids and bases are used to adjust pH levels of biomass broth mixtures or concentrated enzyme liquids throughout the enzyme production process; both acids and bases will cause burns. Dependent upon the compound being used and its degree of hazard potential, protective clothing should be worn and the appropriate control techniques implemented to prevent potential contact or exposure to these agents.

The enzyme molecule consists of a chain of amino acids arranged in a specific geometric configuration. This protein structure, as is with the case of many proteinaceous materials, will cause immunologic responses in susceptible persons due to the inhalation of these antigens. Repeated inhalation of enzyme dust may provoke respiratory allergies (hay fever, asthma) or illnesses (rhinitis) in individuals who have become sensitized to a specific enzyme-protein structure. Sensitization reactions may vary from mild to severe dependent upon the particular individual exposed. Some enzymes, proteolytic enzymes as an example, have been shown to cause contact dermatitis to exposed areas of moist skin, eyes and mucous membranes. The majority of documented case studies of persons exposed to enzymes has focused upon the immunologic responses due to the inhalation of or skin irritation due to the contact to enzymatic dusts.

III. METHODOLOGY

To effectively evaluate the controls and equipment in place at Miles, environmental air samples were taken at strategic locations believed to duplicate workplace exposures and indicate emission sources. The major pieces of equipment used in this evaluation are listed in Table I of the Appendix.

Viable Sampling

To determine concentrations of airborne microorganisms around unit processes, the Andersen 2-stage viable sampler was used at a flow rate of 1 cubic foot per minute (CFM). Locations for viable samples include the laboratory, inoculum tank, seed fermentors, fermentor tanks, fermentor sample port, centrifuge, vacuum filter, the drop tank room, areas outdoors, and a laboratory office, -- the latter three sample sites were selected to give approximations of normal background levels. Some area samples were taken as side-by-side (two Andersens) samples to monitor variability of the microbial air samplers. The samples were collected over a four day period, most sites were sampled for two days. Sample times varied from 20 minutes down to 10 minutes depending on the sample location. For example, a sampling time of 20 minutes was used in areas where microbial concentrations (in the laboratory) were expected to be low and a 10 minute sampling time was used in areas of higher microbial concentrations (around centrifuge operations). Standard Methods Agar was used as the sampling media in each stage of the viable sampler. The 50% effective cutoff diameter for the top stage of the Andersen viable sampler is 8.0 um -- larger, non-respirable particles are collected on the top stage, smaller, respirable particles are collected on the bottom stage.

Analysis of the viable samples was conducted on-site by a Center for Disease Control (CDC) microbiologist and a NIOSH biologist. The primary goal of the

microbiological analysis was to determine the numbers of the production microorganism in the air at different locations in the plant. All air sampling plates were counted at 24 hours using standard colony counters. Colonial morphology was compared with that of the production strain of the same age and on the same medium. Where possible, colonies resembling the production strain were included as a separate count. A percentage of these typical colonies were streaked to Standard Methods Agar (with Manganese) for isolation and identification. Colonies were identified by gram stain and/or the Rapid CH kit manufactured by API System, S.A. This identification scheme consists of 49 biochemical tests read at 24 and 48 hours. Results were compared to the Rapid CH profile of the index strain.

Sample results are in terms of Colony-Forming Units per cubic meter of air (CFU/m^3) with percentages of the production strain, where available. Sample concentrations around process operations are compared to background samples to help ascertain the degree of microorganism release from manufacturing processes.

Total Dust Sampling

Total dust samples were collected using General Metal Works high-volume samplers and high efficiency (pre-weighed) 8" by 10" glass fiber filters at a flow rate of approximately 40 CFM. The samplers were strategically positioned at fixed locations in the plant best suited to estimate exposure conditions and isolate points of dust release. Locations for the high-volume samplers included the fermentor, centrifuge room, rotary filter, dump station, and background locations. Samples were collected for up to eight hours per workshift over a four day period. The 8" x 10" glass fiber filters were weighed before sampling on a Mettler AE 163 balance. The instrumental precision for one sitting is 0.01 mg. After sampling, the filters were equilibrated in the laboratory environment (cooled and dehumidified) and reweighed on the same balance. The difference in filter weights were recorded as total weight per filter.

Total dust samples were also collected on 37 mm, 5 um pore size PVC filters at an approximate flow rate of 2.5 liters per minute (lpm) with Dupont 2500 pumps according to the NIOSH method No. 0500.[9] Samples were collected for up to eight hours. The pumps were calibrated prior to the field survey. Sample locations included the bag opening station and bag dump station. The PVC filters were pre-weighed in the Miles laboratory (on a Mettler AE 163 balance) and re-weighed under the same conditions after sampling. The difference between the initial weight and the weight after sampling is given as total weight per filter.

IV. RESULTS

The results of the viable air sampling analysis are reported in the appendix in Table II and are summarized in Table 1. Arithmetic averages were determined for each particular location and day; and for each location a geometric mean concentration was calculated from the daily averages. Background samples were collected both inside and outside the plant. Because

Table 1. Viable Sampling Summary

Sample Location	Date	Number	Average	St. Dev.	Geo. Mean
Sample Port-Fermentor 3	18-Nov	4	299.8	117.7	372.51
	21-Nov	4	462.9	62.3	
Agitator Shaft-Fermentor 3	18-Nov	16	161.7	108.3	256.51
	21-Nov	12	406.9	116.4	
Centrifuge	19-Nov	10	823.7	482.4	952.83
	20-Nov	22	1102.2	1160.7	
Rotary Vacuum Belt Filter	20-Nov	9	3040.0	1402.0	2797.00
by knife edge	21-Nov	12	2154.0	364.0	2124.00
Rotary Vacuum Belt Filter	20-Nov	9	335.0	31.0	333.00
at conveyor transfer point	21-Nov	12	319.0	83.0	308.00
Background-Drop Tank Room 3rd Floor	19-Nov	6	113.9	162.6	205.65
	21-Nov	15	371.3	280.3	
Background-Outside West 2nd Floor	19-Nov	4	38.4	4.4	50.99
	20-Nov	3	67.7	10.2	
Background-Laboratory 4th Floor	19-Nov	2	30.0	3.5	20.35
	20-Nov	5	13.8	9.7	
Background-Room Adjacent to Incubation	18-Nov	4	2.2	2.3	
Agitator Shaft-Seed Fermentor 1	19-Nov	30	141.6	167.4	
Clean Room	20-Nov	6	0.0	0.0	

the entire fermentation process was under roof except for some holding tanks, the primary background samples were taken inside in the drop tank room away from the major process equipment. Samples were taken on two days in the drop tank room: on November 19, microbial levels averaged 114 CFU/m^3 with an arithmetic standard deviation of 163 CFU/m^3; and on November 21, averaged 371 CFU/m^3 with a standard deviation of 280 CFU/m^3. The geometric mean concentration for the drop tank room for both dates was 206 CFU/m^3. On November 21, the drop tank room results showed microbial levels decreased from relatively high levels (355-875 CFU/m^3) in the morning to lower levels (72-127 CFU/m^3) in the afternoon. This major decrease in microbial levels could not be explained.

Outside background samples were collected on two days. On November 19, microbial levels averaged 38 CFU/m^3 with an arithmetic standard deviation of 4 CFU/m^3; and on November 20, averaged 68 CFU/m^3 with a standard deviation of 10 CFU/m^3. Outside temperatures were 65° and 30°F on November 19 and 20, respectively. The geometric mean for both dates was 51 CFU/m^3.

Viable samples collected around selected unit processes ranged from averages of 0 CFU/m^3 in the clean room to 1,440 CFU/m^3 around the rotary vacuum filter. The arithmetic average microbial concentrations around the vacuum filters were 1,690 CFU/m^3 and 1,240 CFU/m^3 on November 20 and November 21, respectively. (The geometric mean for the two dates was 1,440 CFU/m^3.) The next highest levels occurred in the centrifuge room with 824 and 1,100 CFU/m^3 on November 19 and 20, respectively. The geometric mean concentration for both days was 953 CFU/m^3. The centrifuges were operating while samples were being collected.

Viable samples were also collected for two days at the fermentor sample port, fermentor agitator shaft, and in the laboratory. The geometric mean microbial concentration (calculated from the daily arithmetic average) was 372 CFU/m^3 for the fermentor sample port, 257 CFU/m^3 at the fermentor agitator shaft, and 20 CFU/m^3 in the laboratory. Samples taken at the seed fermentor agitator shaft for one day averaged 142 CFU/m^3.

Microbial levels at each sample location in the process building were compared with average background levels (drop tank area - 3rd floor) inside the building. T-test results showed the average microbial concentrations near the centrifuges and at the vacuum filter knife edge were significantly higher than indoor background levels; average microbial levels at the sample port, fermentor agitator shaft, seed fermentor agitator shaft, and vacuum filter transfer point were not significantly higher than the indoor background levels. Clean room microbial levels were significantly lower than background levels in the 4th floor laboratory. All samples were blank corrected.

Quantitative results for the production organism were obtained for November 18 and 19, qualitative results were obtained for November 21. (The microbiologist was hospitalized during the survey and quantitative production organism data were not available for November 20 and 21.) The percentage of counted colonies identified as the production organism was an average of 5 for the centrifuge and 1 to 3 for the sample port, large fermentor agitator shaft, and seed fermentor agitator shaft. None of the indoor or outdoor background

sample colonies were identified as being the production organism. Qualitative results indicated a large number of the counted colonies were the production organism at the rotary vacuum filter knife edge, and some colonies were the production organism at the rotary vacuum filter transfer point.

Results of total dust collected with the high-volume air sampler are reported in Table III. Total dust geometric mean concentrations ranged from 0.08 mg/m^3 by the fermentor agitator shaft and near the rotary filter to 0.50 mg/m^3 outside the dump station room. Geometric mean total dust concentrations in the centrifuge room was 0.09 mg/m^3 and in the drop tank area 0.12 mg/m^3. High-volume total dust samples were taken for four days at each location, except for the fermentor agitator shaft which was sampled for three days.

Total dust samples were also collected on 37 mm pore size PVC filters and are reported in Table IV. The samples were taken in the raw materials area and ranged from less than 0.1 to 0.4 mg/m^3. Results for both the high-volume and PVC samples indicate total dust levels well below the ACGIH recommended standard for nuisance dust of 10 mg/m^3.[8] All samples were blank corrected.

V. CONTROL EVALUATION

PRINCIPLES OF CONTROL

Occupational exposures can be controlled by the application of a number of well-known principles, including engineering measures, work practices, personal protection, and monitoring. These principles may be applied at or near the hazard source, to the general workplace environment, or at the point of occupational exposure to individuals. Controls applied at the source of the hazard, including engineering measures (material substitution, process/equipment modification, isolation or automation, local ventilation) and work practices, are generally the preferred and most effective means of control both in terms of occupational and environmental concerns. Controls which may be applied to hazards that have escaped into the workplace environment include dilution ventilation, dust suppression, and housekeeping. Control measures may also be applied near individual workers, including the use of remote control rooms, isolation booths, supplied-air cabs, work practices, and personal protective equipment.

In general, a system comprised of the above control measures is required to provide worker protection under normal operating conditions as well as under conditions of process upset, failure, and/or maintenance. Process and workplace monitoring devices, personal exposure monitoring, and medical monitoring are important mechanisms for providing feedback concerning effectiveness of the controls in use. Ongoing monitoring and maintenance of controls to insure proper use and operating conditions, and the education and commitment of both workers and management to occupational health are also important ingredients of a complete, effective, and durable control system. These principles of control apply to all situations, but their optimum application varies from case to case.

ENGINEERING CONTROLS

Miles' enzyme production operation is a predominantly closed system once the process has graduated from the laboratory to the large-scale fermentation process steps. There appears to be limited potential for exposure to the microorganisms involved in the fermentation processes or the enzyme products of these microorganisms. All growth and holding tanks are closed during process operations. Batch broth mixtures or concentrated liquid enzymes are transferred between separate unit operations from the fermentation process step to the enzyme standardization process step by a steam sterilized pipe network. Employee contact with the production process operation, once the raw materials have been deposited into their individual container vessels until the vacuum filter step, is minimal other than for equipment maintenance or manual broth sample extraction.

Laboratory Process Steps:

Emission sources of the production microorganisms, Bacillus licheniformis, in the laboratory are: the clean room during transfer of the BL cultures from vial to test tube, test tube to flask, and flask to inoculating devices; and in the laboratory during biochemical analysis of broth samples from the seed and fermentor tanks. The laboratory is on a separate ventilation system from the production area.

The clean room is located in a separate room next to the main laboratory area and the door to the room is kept closed. Workers entering the clean room must wear disposable shoe covers. Air samples collected in the clean room for one day showed microbial levels to be zero CFU/m^3 (Table 1). General area samples taken in the laboratory (4th floor) on separate days showed microbial levels averaged 30 and 14 CFU/m^3 on the first and second sample dates, respectively. The arithmetic standard deviations for the two days were 4 and 10 CFU/m^3, respectively. Microbial levels for both days was 20 mg/m^3 (geometric mean).

A third set of samples were collected in a small office connected to the laboratory. The door between the laboratory and office is kept open. Microbial levels in this room taken for one day averaged 2 CFU/m^3 and the arithmetic standard deviation was 2 CFU/m^3.

Fermentation Process Step:

Minor potential for release of aerosolized viables exists at certain sites around the seed and fermentor tanks. These sites include the broth sampling ports and agitator shafts. Broth sampling at the fermentor tanks was an intermittent operation. The sample port valve is closed and continuously steam sealed when not in use to prevent contamination of the culture broth. The steam seal also appeared to be effective in preventing the escape of viables from the sample port. During sampling, the steam seal is turned off and a shake flask and/or beaker is filled with broth. It takes about 5 seconds to fill a beaker. After sampling the valve is shut off, the steam is increased to bleed the valve of remaining contaminants. A local exhaust hood is attached to the sampling port valve to help reduce emissions during the

manual broth sampling. The exhaust hood appeared to capture the bleed stream; but was unable to capture the purge stream. Average arithmetic concentrations for microbial samples were 300 and 463 CFU/m^3 on the first and second sample days, respectively. Microbial levels during manual sampling at the fermentors for two days averaged (geometric mean) 373 CFU/m^3. The percentage of counted colonies identified as the production organism averaged 2 for the sample port.

The agitator shafts for the seed fermentors and the large fermentors have double, mechanical steam-sealed tungsten-against carbon seals. Sample results around the seals of the seed fermentor agitator shaft showed an average (arithmetic) concentration (one day sample) of 142 CFU/m^3 with an arithmetic standard deviation of 167 CFU/m^3. Around the seals of the large fermentor agitator shaft the average microbial level and the arithmetic standard deviation for the first day sampled were 162 CFU/m^3 and 108 CFU/m^3, respectively, and for the second day were 407 CFU/m^3 and 116 CFU/m^3, respectively. The geometric mean concentration for both days was 257 CFU/m^3. The percentage of counted colonies identified as the production organism was an average of 3 at the seed fermentor agitator shaft, and less than 1 at the large fermentor agitator shaft. Total dust samples, collected next to the fermentor agitator shaft on three days, showed a geometric mean concentration of 0.8 mg/m^3.

Recovery Process Step:

In process recovery, the product enzyme, α-amylase, was separated from the biomass broth mixture by a rotary vacuum drum filter. The enzyme slurry from the fermentor or drop tank is pumped to the vacuum filter (diatomaceous earth is used as a precoat) where the solids collect on the drum, and the liquid portion (enzyme) is pumped to the concentration process. The solids are removed from the vacuum filter drum by a stellite blade and drop to a conveyor belt which discharges to a dumpster. Potential sources for microbial emissions are the vacuum filter itself, the filter solids dropping on the belt, and the conveyor belt. Samples were collected on the rotary vacuum filter for two days. On the first day, the average microbial level was 1,688 CFU/m^3 and the arithmetic standard deviation was 1,677 CFU/m^3; the second day the average level was 1,237 CFU/m^3 and standard deviation 955 CFU/m^3. Samples taken at the vacuum filter were taken at two locations: one right next to the vacuum filter belt near the stellite blade; the second was several feet from the vacuum filter at the conveyor transfer point. Average microbial concentrations for samples next to the vacuum filter were 3,040 CFU/m^3 on day 1, and 2,154 CFU/m^3 on day 2; and at the conveyor transfer point were 335 CFU/m^3 on day 1 and 319 CFU/m^3 on day 2. Qualitative results showed many of the counted colonies were the production organism at the knife edge, while some of the counted colonies were identified as the production organism at the transfer point.

Total dust concentrations collected near the vacuum filter using the high-volume sampler averaged 0.08 mg/m^3 (geometric mean).

Each centrifuge was equipped with a hood surrounding the centrifuge discharge. The centrifuge room was sampled on two days with samplers placed

at two locations: one next to centrifuge #1 and the other next to centrifuge #2. Average microbial levels for both samplers was 824 CFU/m^3 (arithmetic standard deviation was 482 CFU/m^3) on November 19; 1,102 CFU/m^3 (standard deviation was 1,161 CFU/m^3) on November 20. These levels are well above background microbial levels in the production area which averaged 114 CFU/m^3 on November 19, and 371 CFU/m^3 on November 21. Both centrifuge and production area background samples were taken on November 19: centrifuge samples were collected between 1530 and 1630 hours and background samples from 1030 to 1330 hours. The percentage of counted colonies identified as the production organism averaged 5. Total dust samples taken in the centrifuge room averaged (geometric mean) 0.09 mg/m^3.

All dumping stations for raw materials are equipped with local exhaust ventilation hoods with bag filters built into each exhaust. The hoppers, into which the raw materials are deposited, are equipped with interlocked doors which turn on the exhaust fans when the doors are opened. Total dust samples taken outside the door to the dump station room averaged 0.47 mg/m^3 (geometric mean) and ranged from 0.24 to 0.76 mg/m^3. (High-volume samples for total dust could not be taken in the dump station room because the sample pumps were not intrinsically safe.) The total dust geometric mean concentration in the dump station room for samples collected on PVC filters was 0.20 mg/m^3.

WORK PRACTICES

Miles maintains a relatively clean occupational environment -- generally, to reduce the threat of contaminating an enzyme broth. But, this attitude also benefits the workers by helping to prevent the unnecessary exposure to hazardous agents or conditions. If an enzyme spill occurs, it is washed (flushed) down into the plant sewer system. Diatomaceous earth spills are removed with an industrial vacuum cleaner.

MONITORING

The environmental health program for the Miles enzyme operation is monitored on the corporate level. The responsibilities of the Safety and Health and Medical Departments are for the entire plant complex and its employees. As part of the environmental health program, settling plate samples have been collected in the enzyme production area. These samples indicated strictly enzyme producing or non-producing colonies. Miles is attempting to develop a total (quantitative) colony count sampling methodology. They are also attempting to develop a procedure (activity test) for detecting minute quantities of enzyme in the ambient air -- some bulk samples have been conducted.

Pre-placement medical evaluations are conducted including a complete medical history, pulmonary function test, audiometric test, visual exam, cardiogram, CBC, urine analysis, and a SMA-14. Periodic medical evaluations are selectively performed. If a problem is encountered with an enzyme production employee, medical treatment is conducted individually on a case-by-case basis, based on the recommendation of the treating physician.

PERSONAL PROTECTIVE EQUIPMENT

Inhalation of diatomaceous earth (amorphous silica) is possible during the dumping of bags of diatomaceous earth. Disposable respirators (3M Model 8710) are used when employees are engaged in this operation. Goggles, face shields, and gloves are required during the bag dumping and handling of acids and caustics.

Miles employs a confined space procedure when an employee is required to enter a tank for maintenance or other purposes. Emergency escape units are available during tank entry operations.

VI. CONCLUSIONS

Microbial sample concentrations around selected locations were compared to background concentrations using the t-test. Only one unit process, the centrifuge, showed viable levels to be significantly above indoor background levels. Viable levels at the vacuum filter knife edge were significantly above the background; however, viable concentrations just a few feet from the vacuum filter belt were not significantly above background. Viable concentrations at the fermentor agitator shaft, seed fermentor agitator shaft, and fermentor sample port were not significantly above background concentrations.

Microbial levels in the clean room were significantly below the laboratory background levels. Average outdoor microbial background levels were below average indoor background levels; indicating the outdoors (ambient) air was not a major source of viables in the production building. The results indicate overall effective containment of the production organisms used at Miles, especially since B. licheniformis is not pathogenic. Should this same technology be used for other organisms, it would be advisable to assure that workplace levels such as those seen in this survey would be safe for the other organisms.

Total dust levels at the sample locations, including the raw materials dumping stations, were much below the Threshold Limit Value of 10 mg/m^3 with the highest level one-ninth of the TLV®.[8]

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Table I. Equipment Used on Field Survey

Item	Model	
Automatic balance	Mettler AE 163	Gravimetric analysis
Automatic psychrometer	Vista Scientific Corp.	Temperature and humidity measurements
Colony counter	New Brunswick Scientific	Colony counts and identification
High-volume air sampler	General Metal Works	Total dust sampling
Personal sampling pump	DuPont 2500	Total dust sampling
Smoke tubes	Draeger	Airflow patterns
Viable cascade impactor	Andersen 2-stage	Microbial air sampling

Table II. Viable Sampling Results

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Sample Port - Fermentor 3	18-Nov	1000	1340	15	0.42	39	64	150.8	1.00
Sample Port - Fermentor 3	18-Nov	1001	1340	15	0.42	25			0
Sample Port - Fermentor 3	18-Nov	1002	1340	15	0.42	43	103	242.6	2.00
Sample Port - Fermentor 3	18-Nov	1003	1340	15	0.42	60			7.00
Sample Port - Fermentor 3	18-Nov	1028	1405	15	0.42	152	199	468.8	0
Sample Port - Fermentor 3	18-Nov	1029	1405	15	0.42	47			0
Sample Port - Fermentor 3	18-Nov	1030	1405	15	0.42	102	143	336.9	0
Sample Port - Fermentor 3	18-Nov	1031	1405	15	0.42	41			0
Agitator Shaft - Fermentor 3	18-Nov	1004	1310	15	0.42	29	64	150.8	0
Agitator Shaft - Fermentor 3	18-Nov	1005	1310	15	0.42	35			0
Agitator Shaft - Fermentor 3	18-Nov	1006	1310	15	0.42	14	41	96.6	0
Agitator Shaft - Fermentor 3	18-Nov	1007	1310	15	0.42	27			0
Agitator Shaft - Fermentor 3	18-Nov	1008	1344	15	0.42	12	37	87.2	0
Agitator Shaft - Fermentor 3	18-Nov	1009	1344	15	0.42	25			0
Agitator Shaft - Fermentor 3	18-Nov	1010	1344	15	0.42	30	52	122.5	0
Agitator Shaft - Fermentor 3	18-Nov	1011	1344	15	0.42	22			0
Agitator Shaft - Fermentor 3	18-Nov	1012	1212	15	0.42	69	150	353.4	1.00
Agitator Shaft - Fermentor 3	18-Nov	1013	1212	15	0.42	81			1.00
Agitator Shaft - Fermentor 3	18-Nov	1014	1212	15	0.42	124	210	494.7	1.00
Agitator Shaft - Fermentor 3	18-Nov	1015	1212	15	0.42	86			1.00
Agitator Shaft - Fermentor 3	18-Nov	1016	1431	15	0.42	40	72	169.6	0
Agitator Shaft - Fermentor 3	18-Nov	1017	1431	15	0.42	32			0
Agitator Shaft - Fermentor 3	18-Nov	1018	1431	15	0.42	48	89	209.7	0
Agitator Shaft - Fermentor 3	18-Nov	1019	1431	15	0.42	41			0
Agitator Shaft - Fermentor 3	18-Nov	1020	1446	15	0.42	18	37	87.2	0
Agitator Shaft - Fermentor 3	18-Nov	1021	1446	15	0.42	19			0
Agitator Shaft - Fermentor 3	18-Nov	1022	1446	15	0.42	18	43	101.3	0
Agitator Shaft - Fermentor 3	18-Nov	1023	1446	15	0.42	25			0
Agitator Shaft - Fermentor 3	18-Nov	1024	1503	15	0.42	15	61	143.7	0

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Agitator Shaft - Fermentor 3	18-Nov	1025	1503	15	0.42	46			0
Agitator Shaft - Fermentor 3	18-Nov	1026	1503	15	0.42	25	74	174.3	0
Agitator Shaft - Fermentor 3	18-Nov	1027	1503	15	0.42	49			0
Agitator Shaft - Fermentor 3	18-Nov	1032	1520	15	0.42	23	36	84.8	0
Agitator Shaft - Fermentor 3	18-Nov	1033	1520	15	0.42	13			0
Agitator Shaft - Fermentor 3	18-Nov	1034	1520	15	0.42	22	36	84.8	0
Agitator Shaft - Fermentor 3	18-Nov	1035	1520	15	0.42	14			1.00
Agitator Shaft - Fermentor 3	18-Nov	1040	1603	15	0.42	16	48	113.1	0
Agitator Shaft - Fermentor 3	18-Nov	1041	1603	15	0.42	32			1.00
Agitator Shaft - Fermentor 3	18-Nov	1042	1603	15	0.42	15	48	113.1	1.00
Agitator Shaft - Fermentor 3	18-Nov	1043	1603	15	0.42	33			0
Background - room adj to incubation	18-Nov	2000	1450	20	0.57	2	2	3.5	0
Background - room adj to incubation	18-Nov	2001	1450	20	0.57	0			1.00
Background - room adj to incubation	18-Nov	2002	1517	20	0.57	0	0	0.0	2.00
Background - room adj to incubation	18-Nov	2003	1517	20	0.57	0			0
Background - room adj to incubation	18-Nov	2004	1537	20	0.57	3	3	5.3	0
Background - room adj to incubation	18-Nov	2005	1537	20	0.57	0			0
Background - room adj to incubation	18-Nov	2008	1558	20	0.57	0	0	0.0	0
Background - room adj to incubation	18-Nov	2009	1558	20	0.57	0			0
Incubation Room	19-Nov	2010	0920	20	0.57	6	13	23.0	0
Incubation Room	19-Nov	2011	0920	20	0.57	7			0
Incubation Room	19-Nov	2014	0955	20	0.57	18	30	53.0	0
Incubation Room	19-Nov	2015	0955	20	0.57	12			0
Background - laboratory 4th floor	19-Nov	2016	1609	20	0.57	9	19	33.6	0
Background - laboratory 4th floor	19-Nov	2017	1609	20	0.57	10			0
Background - laboratory 4th floor	19-Nov	2020	1635	20	0.57	6	15	26.5	0
Background - laboratory 4th floor	19-Nov	2021	1635	20	0.57	9			0
Background - drop tank room 3rd fl	19-Nov	2500	1026	15	0.42	53	202	475.9	0
Background - drop tank room 3rd fl	19-Nov	2501	1026	15	0.42	149			0

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Background - drop tank room 3rd fl	19-Nov	2502	1047	15	0.42	3	28	66.0	0
Background - drop tank room 3rd fl	19-Nov	2503	1047	15	0.42	25			0
Background - drop tank room 3rd fl	19-Nov	2504	1107	15	0.42	7	21	49.5	0
Background - drop tank room 3rd fl	19-Nov	2505	1107	15	0.42	14			0
Background - drop tank room 3rd fl	19-Nov	2508	1247	15	0.42	4	20	47.1	0
Background - drop tank room 3rd fl	19-Nov	2509	1247	15	0.42	16			0
Background - drop tank room 3rd fl	19-Nov	2510	1307	15	0.42	5	9	21.2	0
Background - drop tank room 3rd fl	19-Nov	2511	1307	15	0.42	4			0
Background - drop tank room 3rd fl	19-Nov	2514	1332	15	0.42	6	10	23.6	0
Background - drop tank room 3rd fl	19-Nov	2515	1332	15	0.42	4			0
Background - outside west 2nd floor	19-Nov	2700	1359	20	0.57	11	21	37.1	0
Background - outside west 2nd floor	19-Nov	2701	1359	20	0.57	10			0
Background - outside west 2nd floor	19-Nov	2702	1429	20	0.57	9	18	31.8	0
Background - outside west 2nd floor	19-Nov	2703	1429	20	0.57	9			0
Background - outside west 2nd floor	19-Nov	2704	1457	20	0.57	4	24	42.4	0
Background - outside west 2nd floor	19-Nov	2705	1457	20	0.57	20			0
Background - outside west 2nd floor	19-Nov	2706	1520	20	0.57	13	24	42.4	0
Background - outside west 2nd floor	19-Nov	2707	1520	20	0.57	11			0
Agitator Shaft - seed fermentor 1	19-Nov	3000	0925	15	0.42	52	117	275.6	0
Agitator Shaft - seed fermentor 1	19-Nov	3001	0925	15	0.42	65			7.00
Agitator Shaft - seed fermentor 1	19-Nov	3002	0925	15	0.42	55	124	292.1	4.00
Agitator Shaft - seed fermentor 1	19-Nov	3003	0925	15	0.42	69			13.00
Agitator Shaft - seed fermentor 1	19-Nov	3004	0942	15	0.42	9	29	68.3	1.00
Agitator Shaft - seed fermentor 1	19-Nov	3005	0942	15	0.42	20			13.00
Agitator Shaft - seed fermentor 1	19-Nov	3006	0942	15	0.42	10	28	66.0	0
Agitator Shaft - seed fermentor 1	19-Nov	3007	0942	15	0.42	18			5.00
Agitator Shaft - seed fermentor 1	19-Nov	3008	0959	15	0.42	22	39	91.9	0
Agitator Shaft - seed fermentor 1	19-Nov	3009	0959	15	0.42	17			0
Agitator Shaft - seed fermentor 1	19-Nov	3010	0959	15	0.42	16	35	82.4	0

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Agitator Shaft - seed fermentor 1	19-Nov	3011	0959	15	0.42	19			0
Agitator Shaft - seed fermentor 1	19-Nov	3012	1015	15	0.42	25	61	143.7	0
Agitator Shaft - seed fermentor 1	19-Nov	3013	1015	15	0.42	36			0
Agitator Shaft - seed fermentor 1	19-Nov	3014	1015	15	0.42	16	59	139.0	0
Agitator Shaft - seed fermentor 1	19-Nov	3015	1015	15	0.42	43			0
Agitator Shaft - seed fermentor 1	19-Nov	3016	1031	15	0.42	128	300	706.7	0
Agitator Shaft - seed fermentor 1	19-Nov	3017	1031	15	0.42	172			0
Agitator Shaft - seed fermentor 1	19-Nov	3018	1031	15	0.42	127	307	723.2	0
Agitator Shaft - seed fermentor 1	19-Nov	3019	1031	15	0.42	180			0
Agitator Shaft - seed fermentor 1	19-Nov	3020	1047	15	0.42	23	89	209.7	0
Agitator Shaft - seed fermentor 1	19-Nov	3021	1047	15	0.42	66			0
Agitator Shaft - seed fermentor 1	19-Nov	3022	1047	15	0.42	35	94	221.4	0
Agitator Shaft - seed fermentor 1	19-Nov	3023	1047	15	0.42	59			0
Agitator Shaft - seed fermentor 1	19-Nov	3028	1103	15	0.42	23	65	153.1	0
Agitator Shaft - seed fermentor 1	19-Nov	3029	1103	15	0.42	42			0
Agitator Shaft - seed fermentor 1	19-Nov	3030	1103	15	0.42	16	50	117.8	0
Agitator Shaft - seed fermentor 1	19-Nov	3031	1103	15	0.42	34			0
Agitator Shaft - seed fermentor 1	19-Nov	3032	1119	15	0.42	14	31	73.0	2.00
Agitator Shaft - seed fermentor 1	19-Nov	3033	1119	15	0.42	17			0
Agitator Shaft - seed fermentor 1	19-Nov	3034	1119	15	0.42	17	44	103.7	2.00
Agitator Shaft - seed fermentor 1	19-Nov	3035	1119	15	0.42	27			0
Agitator Shaft - seed fermentor 1	19-Nov	3036	1254	15	0.42	17	30	70.7	0
Agitator Shaft - seed fermentor 1	19-Nov	3037	1254	15	0.42	13			0
Agitator Shaft - seed fermentor 1	19-Nov	3038	1254	15	0.42	12	32	75.4	0
Agitator Shaft - seed fermentor 1	19-Nov	3039	1254	15	0.42	20			0
Agitator Shaft - seed fermentor 1	19-Nov	3040	1310	15	0.42	1	10	23.6	0
Agitator Shaft - seed fermentor 1	19-Nov	3041	1310	15	0.42	9			0
Agitator Shaft - seed fermentor 1	19-Nov	3042	1310	15	0.42	13	29	68.3	0
Agitator Shaft - seed fermentor 1	19-Nov	3043	1310	15	0.42	16			0

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Agitator Shaft - seed fermentor 1	19-Nov	3044	1326	15	0.42	18	26	61.2	0
Agitator Shaft - seed fermentor 1	19-Nov	3045	1326	15	0.42	8			0
Agitator Shaft - seed fermentor 1	19-Nov	3046	1326	15	0.42	9	15	35.3	0
Agitator Shaft - seed fermentor 1	19-Nov	3047	1326	15	0.42	6			0
Agitator Shaft - seed fermentor 1	19-Nov	3048	1342	15	0.42	16	26	61.2	0
Agitator Shaft - seed fermentor 1	19-Nov	3049	1342	15	0.42	10			0
Agitator Shaft - seed fermentor 1	19-Nov	3050	1342	15	0.42	17	20	47.1	0
Agitator Shaft - seed fermentor 1	19-Nov	3051	1342	15	0.42	3			0
Agitator Shaft - seed fermentor 1	19-Nov	3052	1358	15	0.42	8	14	33.0	0
Agitator Shaft - seed fermentor 1	19-Nov	3053	1358	15	0.42	6			0
Agitator Shaft - seed fermentor 1	19-Nov	3054	1358	15	0.42	6	11	25.9	0
Agitator Shaft - seed fermentor 1	19-Nov	3055	1358	15	0.42	5			0
Agitator Shaft - seed fermentor 1	19-Nov	3060	1414	15	0.42	8	27	63.6	0
Agitator Shaft - seed fermentor 1	19-Nov	3061	1414	15	0.42	19			0
Agitator Shaft - seed fermentor 1	19-Nov	3062	1414	15	0.42	11	29	68.3	0
Agitator Shaft - seed fermentor 1	19-Nov	3063	1414	15	0.42	18			0
Agitator Shaft - seed fermentor 1	19-Nov	3064	1429	15	0.42	16	31	73.0	0
Agitator Shaft - seed fermentor 1	19-Nov	3065	1429	15	0.42	15			0
Agitator Shaft - seed fermentor 1	19-Nov	3066	1429	15	0.42	17	31	73.0	0
Agitator Shaft - seed fermentor 1	19-Nov	3067	1429	15	0.42	14			0
Centrifuge	19-Nov	6000	1532	10	0.28	198	577	2038.9	0
Centrifuge	19-Nov	6001	1532	10	0.28	379			0
Centrifuge	19-Nov	6002	1532	10	0.28	162	372	1314.5	NQ*
Centrifuge	19-Nov	6003	1532	10	0.28	210			0
Centrifuge	19-Nov	6004	1543	10	0.28	106	243	858.7	0
Centrifuge	19-Nov	6005	1543	10	0.28	137			5.00
Centrifuge	19-Nov	6006	1543	10	0.28	104	249	879.9	50.00
Centrifuge	19-Nov	6007	1543	10	0.28	145			7.00
Centrifuge	19-Nov	6010	1553	10	0.28	56	112	395.8	3.00

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Centrifuge	19-Nov	6011	1553	10	0.28	56			8.00
Centrifuge	19-Nov	6008	1553	10	0.28	71	144	508.8	11.00
Centrifuge	19-Nov	6009	1553	10	0.28	73			0
Centrifuge	19-Nov	6012	1603	10	0.28	66	125	441.7	0
Centrifuge	19-Nov	6013	1603	10	0.28	59			0
Centrifuge	19-Nov	6014	1603	10	0.28	132	207	731.4	7.00
Centrifuge	19-Nov	6015	1603	10	0.28	75			0
Centrifuge	19-Nov	6016	1614	10	0.28	74	156	551.2	4.00
Centrifuge	19-Nov	6017	1614	10	0.28	82			1.00
Centrifuge	19-Nov	6018	1614	10	0.28	87	146	515.9	2.00
Centrifuge	19-Nov	6019	1614	10	0.28	59			0
Background - laboratory 4th floor	20-Nov	2022	1437	20	0.57	17	18	31.8	NQ*
Background - laboratory 4th floor	20-Nov	2023	1437	20	0.57	1			NQ*
Background - laboratory 4th floor	20-Nov	2024	1503	20	0.57	5	9	15.9	NQ*
Background - laboratory 4th floor	20-Nov	2025	1503	20	0.57	4			NQ*
Background - laboratory 4th floor	20-Nov	2026	1528	20	0.57	4	4	7.1	NQ*
Background - laboratory 4th floor	20-Nov	2027	1528	20	0.57	0			NQ*
Background - laboratory 4th floor	20-Nov	2030	1600	20	0.57	2	5	8.8	NQ*
Background - laboratory 4th floor	20-Nov	2031	1600	20	0.57	3			NQ*
Background - laboratory 4th floor	20-Nov	2032	1625	20	0.57	3	3	5.3	NQ*
Background - laboratory 4th floor	20-Nov	2033	1625	20	0.57	0			NQ*
Background - outside west 2nd floor	20-Nov	2710	1251	20	0.57	28	37	65.4	NQ*
Background - outside west 2nd floor	20-Nov	2711	1251	20	0.57	9			NQ*
Background - outside west 2nd floor	20-Nov	2712	1320	20	0.57	24	46	81.3	NQ*
Background - outside west 2nd floor	20-Nov	2713	1320	20	0.57	22			NQ*
Background - outside west 2nd floor	20-Nov	2714	1348	20	0.57	15	32	56.5	NQ*
Background - outside west 2nd floor	20-Nov	2715	1348	20	0.57	17			NQ*
Rotary Vacuum Belt Filter	20-Nov	6500	1258	15	0.42	2703	2790	6572.4	NQ*
Rotary Vacuum Belt Filter	20-Nov	6501	1258	15	0.42	87			NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Rotary Vacuum Belt Filter	20-Nov	6502	1258	15	0.42	97	151	355.7	NQ*
Rotary Vacuum Belt Filter	20-Nov	6503	1258	15	0.42	54			NQ*
Rotary Vacuum Belt Filter	20-Nov	6504	1313	15	0.42	1551	1635	3851.6	NQ*
Rotary Vacuum Belt Filter	20-Nov	6505	1313	15	0.42	84			NQ*
Rotary Vacuum Belt Filter	20-Nov	6506	1313	15	0.42	84	145	341.6	NQ*
Rotary Vacuum Belt Filter	20-Nov	6507	1313	15	0.42	61			NQ*
Rotary Vacuum Belt Filter	20-Nov	6508	1329	15	0.42	1263	1335	3144.9	NQ*
Rotary Vacuum Belt Filter	20-Nov	6509	1329	15	0.42	72			NQ*
Rotary Vacuum Belt Filter	20-Nov	6510	1329	15	0.42	88	133	313.3	NQ*
Rotary Vacuum Belt Filter	20-Nov	6511	1329	15	0.42	45			NQ*
Rotary Vacuum Belt Filter	20-Nov	6512	1345	15	0.42	1247	1333	3140.2	NQ*
Rotary Vacuum Belt Filter	20-Nov	6513	1345	15	0.42	86			NQ*
Rotary Vacuum Belt Filter	20-Nov	6514	1345	15	0.42	96	143	336.9	NQ*
Rotary Vacuum Belt Filter	20-Nov	6515	1345	15	0.42	47			NQ*
Rotary Vacuum Belt Filter	20-Nov	6516	1400	15	0.42	607	693	1632.5	NQ*
Rotary Vacuum Belt Filter	20-Nov	6517	1400	15	0.42	86			NQ*
Rotary Vacuum Belt Filter	20-Nov	6518	1400	15	0.42	87	127	299.2	NQ*
Rotary Vacuum Belt Filter	20-Nov	6519	1400	15	0.42	40			NQ*
Rotary Vacuum Belt Filter	20-Nov	6520	1416	15	0.42	751	877	2066.0	NQ*
Rotary Vacuum Belt Filter	20-Nov	6521	1416	15	0.42	126			NQ*
Rotary Vacuum Belt Filter	20-Nov	6522	1416	15	0.42	109	152	358.1	NQ*
Rotary Vacuum Belt Filter	20-Nov	6523	1416	15	0.42	43			NQ*
Rotary Vacuum Belt Filter	20-Nov	6524	1518	15	0.42	863	926	2181.4	NQ*
Rotary Vacuum Belt Filter	20-Nov	6525	1518	15	0.42	63			NQ*
Rotary Vacuum Belt Filter	20-Nov	6526	1518	15	0.42	112	169	398.1	NQ*
Rotary Vacuum Belt Filter	20-Nov	6527	1518	15	0.42	57			NQ*
Rotary Vacuum Belt Filter	20-Nov	6528	1534	15	0.42	943	1020	2402.8	NQ*
Rotary Vacuum Belt Filter	20-Nov	6529	1534	15	0.42	77			NQ*
Rotary Vacuum Belt Filter	20-Nov	6530	1534	15	0.42	87	131	308.6	NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Rotary Vacuum Belt Filter	20-Nov	6531	1534	15	0.42	44			NQ*
Rotary Vacuum Belt Filter	20-Nov	6532	1550	15	0.42	927	1006	2369.8	NQ*
Rotary Vacuum Belt Filter	20-Nov	6533	1550	15	0.42	79			NQ*
Rotary Vacuum Belt Filter	20-Nov	6534	1550	15	0.42	89	128	301.5	NQ*
Rotary Vacuum Belt Filter	20-Nov	6535	1550	15	0.42	39			NQ*
Clean Room	20-Nov	2400	0838	20	0.57	0	0	0.0	NQ*
Clean Room	20-Nov	2401	0838	20	0.57	0			NQ*
Clean Room	20-Nov	2402	0838	20	0.57	0	0	0.0	NQ*
Clean Room	20-Nov	2403	0908	20	0.57	0			NQ*
Clean Room	20-Nov	2406	0940	20	0.57	0	0	0.0	NQ*
Clean Room	20-Nov	2407	0940	20	0.57	0			NQ*
Clean Room	20-Nov	2408	1008	20	0.57	0	0	0.0	NQ*
Clean Room	20-Nov	2409	1008	20	0.57	0			NQ*
Clean Room	20-Nov	2412	1041	20	0.57	0	0	0.0	NQ*
Clean Room	20-Nov	2413	1041	20	0.57	0			NQ*
Clean Room	20-Nov	2414	1109	20	0.57	0	0	0.0	NQ*
Clean Room	20-Nov	2415	1109	20	0.57	0			NQ*
Centrifuge	20-Nov	6024	0851	10	0.28	101	298	1053.0	NQ*
Centrifuge	20-Nov	6025	0851	10	0.28	197			NQ*
Centrifuge	20-Nov	6026	0851	10	0.28	124	273	964.7	NQ*
Centrifuge	20-Nov	6027	0851	10	0.28	149			NQ*
Centrifuge	20-Nov	6028	0902	10	0.28	92	223	788.0	NQ*
Centrifuge	20-Nov	6029	0902	10	0.28	131			NQ*
Centrifuge	20-Nov	6030	0902	10	0.28	103	201	710.2	NQ*
Centrifuge	20-Nov	6031	0902	10	0.28	98			NQ*
Centrifuge	20-Nov	6032	0913	10	0.28	453	748	2643.1	NQ*
Centrifuge	20-Nov	6033	0913	10	0.28	295			NQ*
Centrifuge	20-Nov	6034	0913	10	0.28	1455	1657	5855.1	NQ*
Centrifuge	20-Nov	6035	0913	10	0.28	202			NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Centrifuge	20-Nov	6036	0924	10	0.28	262	462	1632.5	NQ*
Centrifuge	20-Nov	6037	0924	10	0.28	200			NQ*
Centrifuge	20-Nov	6038	0924	10	0.28	251	428	1512.4	NQ*
Centrifuge	20-Nov	6039	0924	10	0.28	177			NQ*
Centrifuge	20-Nov	6040	0934	10	0.28	100	183	646.6	NQ*
Centrifuge	20-Nov	6041	0934	10	0.28	83			NQ*
Centrifuge	20-Nov	6042	0934	10	0.28	98	152	537.1	NQ*
Centrifuge	20-Nov	6043	0934	10	0.28	54			NQ*
Centrifuge	20-Nov	6044	0944	10	0.28	90	128	452.3	NQ*
Centrifuge	20-Nov	6045	0944	10	0.28	38			NQ*
Centrifuge	20-Nov	6046	0944	10	0.28	73	101	356.9	NQ*
Centrifuge	20-Nov	6047	0944	10	0.28	28			NQ*
Centrifuge	20-Nov	6048	0955	10	0.28	90	153	540.6	NQ*
Centrifuge	20-Nov	6049	0955	10	0.28	63			NQ*
Centrifuge	20-Nov	6050	0955	10	0.28	99	159	561.8	NQ*
Centrifuge	20-Nov	6051	0955	10	0.28	60			NQ*
Centrifuge	20-Nov	6052	1005	10	0.28	69	125	441.7	NQ*
Centrifuge	20-Nov	6053	1005	10	0.28	56			NQ*
Centrifuge	20-Nov	6054	1005	10	0.28	86	126	445.2	NQ*
Centrifuge	20-Nov	6055	1005	10	0.28	40			NQ*
Centrifuge	20-Nov	6056	1016	10	0.28	197	326	1151.9	NQ*
Centrifuge	20-Nov	6057	1016	10	0.28	129			NQ*
Centrifuge	20-Nov	6058	1016	10	0.28	212	365	1289.8	NQ*
Centrifuge	20-Nov	6059	1016	10	0.28	153			NQ*
Centrifuge	20-Nov	6060	1028	10	0.28	84	155	547.7	NQ*
Centrifuge	20-Nov	6061	1028	10	0.28	71			NQ*
Centrifuge	20-Nov	6062	1028	10	0.28	72	133	470.0	NQ*
Centrifuge	20-Nov	6063	1028	10	0.28	61			NQ*
Centrifuge	20-Nov	6064	1039	10	0.28	121	179	632.5	NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Centrifuge	20-Nov	6065	1039	10	0.28	58			NQ*
Centrifuge	20-Nov	6066	1039	10	0.28	83	287	1014.1	NQ*
Centrifuge	20-Nov	6067	1039	10	0.28	204			NQ*
Background - drop tank room 3rd fl	21-Nov	2600	0818	20	0.57	113	142	250.9	NQ*
Background - drop tank room 3rd fl	21-Nov	2601	0818	20	0.57	29			NQ*
Background - drop tank room 3rd fl	21-Nov	2602	0844	20	0.57	247	495	874.6	NQ*
Background - drop tank room 3rd fl	21-Nov	2603	0844	20	0.57	248			NQ*
Background - drop tank room 3rd fl	21-Nov	2606	0917	20	0.57	60	291	514.1	NQ*
Background - drop tank room 3rd fl	21-Nov	2607	0917	20	0.57	231			NQ*
Background - drop tank room 3rd fl	21-Nov	2608	0944	20	0.57	88	201	355.1	NQ*
Background - drop tank room 3rd fl	21-Nov	2609	0944	20	0.57	113			NQ*
Background - drop tank room 3rd fl	21-Nov	2610	1011	20	0.57	266	446	788.0	NQ*
Background - drop tank room 3rd fl	21-Nov	2611	1011	20	0.57	180			NQ*
Background - drop tank room 3rd fl	21-Nov	2612	1038	20	0.57	258	399	704.9	NQ*
Background - drop tank room 3rd fl	21-Nov	2613	1038	20	0.57	141			NQ*
Background - drop tank room 3rd fl	21-Nov	2616	1108	20	0.57	220	302	533.6	NQ*
Background - drop tank room 3rd fl	21-Nov	2617	1108	20	0.57	82			NQ*
Background - drop tank room 3rd fl	21-Nov	2618	1247	20	0.57	208	407	719.1	NQ*
Background - drop tank room 3rd fl	21-Nov	2619	1247	20	0.57	199			NQ*
Background - drop tank room 3rd fl	21-Nov	2620	1312	20	0.57	62	98	173.1	NQ*
Background - drop tank room 3rd fl	21-Nov	2621	1312	20	0.57	36			NQ*
Background - drop tank room 3rd fl	21-Nov	2622	1338	20	0.57	55	97	171.4	NQ*
Background - drop tank room 3rd fl	21-Nov	2623	1338	20	0.57	42			NQ*
Background - drop tank room 3rd fl	21-Nov	2624	1405	20	0.57	53	72	127.2	NQ*
Background - drop tank room 3rd fl	21-Nov	2625	1405	20	0.57	19			NQ*
Background - drop tank room 3rd fl	21-Nov	2628	1436	20	0.57	49	62	109.5	NQ*
Background - drop tank room 3rd fl	21-Nov	2629	1436	20	0.57	13			NQ*
Background - drop tank room 3rd fl	21-Nov	2630	1501	20	0.57	39	57	100.7	NQ*
Background - drop tank room 3rd fl	21-Nov	2631	1501	20	0.57	18			NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Background - drop tank room 3rd fl	21-Nov	2632	1525	20	0.57	30	41	72.4	NQ*
Background - drop tank room 3rd fl	21-Nov	2633	1525	20	0.57	11			NQ*
Background - drop tank room 3rd fl	21-Nov	2634	1552	20	0.57	32	42	74.2	NQ*
Background - drop tank room 3rd fl	21-Nov	2635	1552	20	0.57	10			NQ*
Sample Port - Fermentor 3	21-Nov	6548	1010	10	0.28	106	137	484.1	NQ*
Sample Port - Fermentor 3	21-Nov	6549	1010	10	0.28	31			NQ*
Sample Port - Fermentor 3	21-Nov	6550	1010	10	0.28	115	157	554.8	NQ*
Sample Port - Fermentor 3	21-Nov	6551	1010	10	0.28	42			NQ*
Sample Port - Fermentor 3	21-Nov	6580	1023	10	0.28	86	118	417.0	NQ*
Sample Port - Fermentor 3	21-Nov	6581	1023	10	0.28	32			NQ*
Sample Port - Fermentor 3	21-Nov	6582	1023	10	0.28	75	112	395.8	NQ*
Sample Port - Fermentor 3	21-Nov	6583	1023	10	0.28	37			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6540	0934	15	0.42	105	200	471.1	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6541	0934	15	0.42	95			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6542	0934	15	0.42	111	166	391.0	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6543	0934	15	0.42	55			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6544	0950	15	0.42	89	156	367.5	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6545	0950	15	0.42	67			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6546	0950	15	0.42	77	110	259.1	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6547	0950	15	0.42	33			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6552	1015	15	0.42	82	148	348.6	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6553	1015	15	0.42	66			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6554	1015	15	0.42	101	163	384.0	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6555	1015	15	0.42	62			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6556	1041	15	0.42	180	263	619.6	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6557	1041	15	0.42	83			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6558	1041	15	0.42	157	230	541.8	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6559	1041	15	0.42	73			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6564	1057	15	0.42	134	213	501.8	NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Agitator Shaft - Fermentor 3	21-Nov	6565	1057	15	0.42	79			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6566	1057	15	0.42	143	212	499.4	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6567	1057	15	0.42	69			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6568	1115	15	0.42	50	100	235.6	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6569	1115	15	0.42	50			NQ*
Agitator Shaft - Fermentor 3	21-Nov	6570	1115	15	0.42	58	112	263.8	NQ*
Agitator Shaft - Fermentor 3	21-Nov	6571	1115	15	0.42	54			NQ*
Rotary Vacuum Belt Filter	21-Nov	6572	1314	15	0.42	623	718	1691.4	NQ*
Rotary Vacuum Belt Filter	21-Nov	6573	1314	15	0.42	95			NQ*
Rotary Vacuum Belt Filter	21-Nov	6574	1314	15	0.42	118	165	388.7	NQ*
Rotary Vacuum Belt Filter	21-Nov	6575	1314	15	0.42	47			NQ*
Rotary Vacuum Belt Filter	21-Nov	6576	1329	15	0.42	703	815	1919.9	NQ*
Rotary Vacuum Belt Filter	21-Nov	6577	1329	15	0.42	112			NQ*
Rotary Vacuum Belt Filter	21-Nov	6578	1329	15	0.42	113	162	381.6	NQ*
Rotary Vacuum Belt Filter	21-Nov	6579	1329	15	0.42	49			NQ*
Rotary Vacuum Belt Filter	21-Nov	6580	1344	10	0.28	687	769	2717.3	NQ*
Rotary Vacuum Belt Filter	21-Nov	6581	1344	10	0.28	82			NQ*
Rotary Vacuum Belt Filter	21-Nov	6582	1344	10	0.28	64	102	360.4	NQ*
Rotary Vacuum Belt Filter	21-Nov	6583	1344	10	0.28	38			NQ*
Rotary Vacuum Belt Filter	21-Nov	6584	1356	10	0.28	607	722	2551.2	NQ*
Rotary Vacuum Belt Filter	21-Nov	6585	1356	10	0.28	115			NQ*
Rotary Vacuum Belt Filter	21-Nov	6586	1356	10	0.28	80	135	477.0	NQ*
Rotary Vacuum Belt Filter	21-Nov	6587	1356	10	0.28	55			NQ*
Rotary Vacuum Belt Filter	21-Nov	6588	1406	10	0.28	447	542	1915.2	NQ*
Rotary Vacuum Belt Filter	21-Nov	6589	1406	10	0.28	95			NQ*
Rotary Vacuum Belt Filter	21-Nov	6590	1406	10	0.28	61	90	318.0	NQ*
Rotary Vacuum Belt Filter	21-Nov	6591	1406	10	0.28	29			NQ*
Rotary Vacuum Belt Filter	21-Nov	6592	1417	10	0.28	639	758	2678.4	NQ*
Rotary Vacuum Belt Filter	21-Nov	6593	1417	10	0.28	119			NQ*

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Rotary Vacuum Belt Filter	21-Nov	6594	1417	10	0.28	74	114	402.8	NQ*
Rotary Vacuum Belt Filter	21-Nov	6595	1417	10	0.28	40			NQ*
Rotary Vacuum Belt Filter	21-Nov	6596	1427	10	0.28	607	725	2561.8	NQ*
Rotary Vacuum Belt Filter	21-Nov	6597	1427	10	0.28	118			NQ*
Rotary Vacuum Belt Filter	21-Nov	6598	1427	10	0.28	58	85	300.4	NQ*
Rotary Vacuum Belt Filter	21-Nov	6599	1427	10	0.28	27			NQ*
Rotary Vacuum Belt Filter	21-Nov	6600	1439	10	0.28	559	648	2289.8	NQ*
Rotary Vacuum Belt Filter	21-Nov	6601	1439	10	0.28	89			NQ*
Rotary Vacuum Belt Filter	21-Nov	6602	1439	10	0.28	66	89	314.5	NQ*
Rotary Vacuum Belt Filter	21-Nov	6603	1439	10	0.28	23			NQ*
Rotary Vacuum Belt Filter	21-Nov	6604	1527	10	0.28	431	544	1922.3	NQ*
Rotary Vacuum Belt Filter	21-Nov	6605	1527	10	0.28	113			NQ*
Rotary Vacuum Belt Filter	21-Nov	6606	1527	10	0.28	42	65	229.7	NQ*
Rotary Vacuum Belt Filter	21-Nov	6607	1527	10	0.28	23			NQ*
Rotary Vacuum Belt Filter	21-Nov	6608	1537	10	0.28	415	492	1738.5	NQ*
Rotary Vacuum Belt Filter	21-Nov	6609	1537	10	0.28	77			NQ*
Rotary Vacuum Belt Filter	21-Nov	6610	1537	10	0.28	45	59	208.5	NQ*
Rotary Vacuum Belt Filter	21-Nov	6611	1537	10	0.28	14			NQ*
Rotary Vacuum Belt Filter	21-Nov	6612	1547	10	0.28	511	562	1985.9	NQ*
Rotary Vacuum Belt Filter	21-Nov	6613	1547	10	0.28	51			NQ*
Rotary Vacuum Belt Filter	21-Nov	6614	1547	10	0.28	55	67	236.7	NQ*
Rotary Vacuum Belt Filter	21-Nov	6615	1547	10	0.28	12			NQ*
Rotary Vacuum Belt Filter	21-Nov	6616	1558	10	0.28	463	532	1879.9	NQ*
Rotary Vacuum Belt Filter	21-Nov	6617	1558	10	0.28	69			NQ*
Rotary Vacuum Belt Filter	21-Nov	6618	1558	10	0.28	35	59	208.5	NQ*
Rotary Vacuum Belt Filter	21-Nov	6619	1558	10	0.28	24			NQ*
Agitator Shaft - Fermentor 3	18-Nov	1036	1550	0	0.00				
Agitator Shaft - Fermentor 3	21-Nov	6560	1041	0	0.00				

* Not quantified

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Agitator Shaft - Fermentor 3	21-Nov	6562	1041	0	0.00				
Agitator Shaft - Fermentor 3	18-Nov	1038	1550	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3026	1102	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3056	1414	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3058	1414	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3024	1102	0	0.00				
Background - drop tank room 3rd floor	19-Nov	2506	1128	0	0.00				
Background - drop tank room 3rd floor	21-Nov	2614	1103	0	0.00				
Background - drop tank room 3rd floor	21-Nov	2604	0910	0	0.00				
Background - drop tank room 3rd floor	19-Nov	2512	1327	0	0.00				
Background - drop tank room 3rd floor	21-Nov	2626	1431	0	0.00				
Background - laboratory 4th floor	19-Nov	2018	1631	0	0.00				
Background - laboratory 4th floor	20-Nov	2028	1555	0	0.00				
Background - outside west 2nd floor	20-Nov	2716	1415	0	0.00				
Background - outside west 2nd floor	19-Nov	2708	1545	0	0.00				
Background - room adj to incubation	18-Nov	2006	1557	0	0.00				
Centrifuge	20-Nov	6070	1044	0	0.00				
Centrifuge	20-Nov	6068	1044	0	0.00				
Centrifuge	19-Nov	6020	1624	0	0.00				
Centrifuge	19-Nov	6022	1624	0	0.00				
Clean Room	20-Nov	2404	0933	0	0.00				
Clean Room	20-Nov	2410	1035	0	0.00				
Incubation Room	19-Nov	2012	0950	0	0.00				
Rotary Vacuum Belt Filter	20-Nov	6538	1550	0	0.00				
Rotary Vacuum Belt Filter	21-Nov	6622	1610	0	0.00				
Rotary Vacuum Belt Filter	21-Nov	6620	1610	0	0.00				
Rotary Vacuum Belt Filter	20-Nov	6536	1550	0	0.00				
Agitator Shaft - Fermentor 3	21-Nov	6561	1041	0	0.00				
Agitator Shaft - Fermentor 3	18-Nov	1037	1550	0	0.00				

(continued)

Table II. (Continued)

Sample Location	Date	Plate	Time	Minutes	m^3 of Air	Corrected CFU	Total CFU	CFU/m^3	BL No.
Agitator Shaft - Fermentor 3	21-Nov	6563	1041	0	0.00				
Agitator Shaft - Fermentor 3	18-Nov	1039	1550	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3059	1414	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3027	1102	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3057	1414	0	0.00				
Agitator Shaft - seed fermentor 1	19-Nov	3025	1102	0	0.00				
Background - drop tank room 3rd floor	21-Nov	2627	1431	0	0.00				
Background - drop tank room 3rd floor	21-Nov	2615	1103	0	0.00				
Background - drop tank room 3rd floor	19-Nov	2513	1327	0	0.00				
Background - drop tank room 3rd floor	19-Nov	2507	1128	0	0.00				
Background - drop tank room 3rd floor	21-Nov	2605	0910	0	0.00				
Background - laboratory 4th floor	19-Nov	2019	1631	0	0.00				
Background - laboratory 4th floor	20-Nov	2029	1555	0	0.00				
Background - outside west 2nd floor	20-Nov	2717	1415	0	0.00				
Background - outside west 2nd floor	19-Nov	2709	1545	0	0.00				
Background - room adj to incubation	18-Nov	2007	1557	0	0.00				
Centrifuge	19-Nov	6021	1624	0	0.00				
Centrifuge	20-Nov	6069	1044	0	0.00				
Centrifuge	20-Nov	6071	1044	0	0.00				
Centrifuge	19-Nov	6023	1624	0	0.00				
Clean Room	20-Nov	2411	1035	0	0.00				
Clean Room	20-Nov	2405	0933	0	0.00				
Incubation Room	19-Nov	2013	0950	0	0.00				
Rotary Vacuum Belt Filter	21-Nov	6621	1610	0	0.00				
Rotary Vacuum Belt Filter	20-Nov	6537	1550	0	0.00				
Rotary Vacuum Belt Filter	20-Nov	6539	1550	0	0.00				
Rotary Vacuum Belt Filter	21-Nov	6623	1610	0	0.00				

Table III. High-Volume Sample Total Dust Results

	Date	Filter No.	Flow Rate (m^3/min)	Sample Volume (m^3)	Total Dust (mg)	Total Dust Concentration (mg/m^3)*
Drop Tank Room	11/18	MF-6	1.557	220	8.2	.037
Drop Tank Room	11/19	MF-10	1.557	759.82	35.0	.046
Drop Tank Room	11/20	MF-25	1.557	739.58	113.0	.153
Drop Tank Room	11/21	MF-27	1.557	731.79	815.1	1.11
Outside Dump Station Room	11/18	MF-7	1.472	213.48	51.9	.243
Outside Dump Station Room	11/19	MF-9	1.472	718.46	254	.354
Outside Dump Station Room	11/20	MF-26	1.472	703.74	529	.752
Outside Dump Station Room	11/21	MF-28	1.472	696.38	530	.761
Rotary Filter	11/18	MF-2	1.416	140	5.3	.038
Rotary Filter	11/19	MF-14	1.416	672.42	42.2	.063
Rotary Filter	11/21	MF-30	1.416	683.75	172	.252
Centrifuge Room	11/18	MF-4	1.416	144.39	12.6	.087
Centrifuge Room	11/19	MF-12	1.416	673.84	29.9	.044
Centrifuge Room	11/20	MF-24	1.416	656.85	113	.172
Centrifuge Room	11/21	MF-29	1.416	680.92	65.6	.096
Agitator Fermentor #3	11/18	MF-5	1.472	226.73	10.4	.046
Agitator Fermentor #3	11/19	MF-15	1.472	515.29	23.5	.046
Agitator Fermentor #3	11/20	MF-22	1.472	612.46	135	.220
Agitator Fermentor #3 Near Wall	11/21	MF-31	1.472	720	112	.156
Blank	11/21	MF-18			-2.1	
Blank	11/19	MF-11			-1.6	
Blank	11/20	MF-20			-1.8	
Blank	11/21	MF-19			-2.4	
Blank	11/18	MF-1			-.4	
Blank	11/18	MF-3			-.4	
Blank	11/19	MF-13			-1.5	
Blank	11/20	MF-21			-1.6	

* These values are corrected for blanks.

Table IV. PVC Total Dust Sampling Results

	Date	PVC Filter No.	Flow Rate (m^3/min)	Sample Volume (m^3)	Total Dust (mg)*	Total Dust Concentration (mg/m^3)*
Right of Baler	11/20	MTF-5	.0025	1.1175	0	0
Dump Station Near Bag Baler	11/19	MTF-1	.0025	1.04	.3	.2885
Near Unvented Hopper	11/19	MTF-2	.0025	1.0225	.3	.2934
On Dump Station MT-3	11/20	MTF-7	.0025	1.14	.4	.3591
Blank	11/20	MTF-6			-.2	
Blank	11/20	MTF-8			-.1	
Blank	11/19	MTF-3			.1	
Blank	11/19	MTF-4			-.1	

* These values are corrected for blanks.