IN-DEPTH SURVEY REPORT:

CONTROL TECHNOLOGY ASSESSMENT OF ENZYME FERMENTATION PROCESSES

AT

Novo Biochemical Industries, Inc.
Franklinton, North Carolina

REPORT WRITTEN BY:
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Division of Physical Sciences and Engineering
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SIC CODE:	2869
SURVEY DATE:	September 9-16, 1985
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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 is 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 specifically 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) involved with the applications of biotechnology and recombinant DNA (rDNA). ECTB's involvement in this NIOSH evaluation is an assessment of 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 study was conducted by the Division of Surveillance, Hazard Evaluation, and Field Studies and was subsequently published in a NIOSH report and a journal article.[6,7]

The ECTB study focused on conventional enzyme fermentation process operations. Several factors contributed to the final decision to focus this research project. 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 existed limited resources (including manpower and finances) with which to conduct this study and time constraints on its completion. Last, there was a good probability of finding well controlled processes in the enzyme industry. 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 will be included as part of the primary objective 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.

BACKGROUND FOR THIS SURVEY

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. This would provide the plant with access to 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.

Novo Biochemical Industries, Inc. (NBI) met all three of the in-depth survey selection criteria requirements.

An in-depth survey of NBI was conducted on September 9-16, 1985 to evaluate the controls and containment capabilities of their α-amylase enzyme manufacturing process. This report documents the information pertinent to that evaluation.

II. PLANT AND PROCESS DESCRIPTION

PLANT DESCRIPTION:
Novo Biochemical Industries, Inc. is located in Franklinton, North Carolina, and has produced enzymes for its parent company, Novo Laboratories, Inc., Wilton, Connecticut, since March, 1979. Novo Laboratories, Inc. is the U.S. branch of Novo Industri A/S, an international manufacturer and supplier of industrial and health care products headquartered in Bagsvaerd, Denmark. Novo Industri A/S is the world's largest producer of enzymes for industrial applications. Enzymes manufactured at NBI are distributed in the U.S. and Canada.

NBI's employee population is separated into 6 departments; administration, production, maintenance, quality control, finance, and personnel. Approximately 50% of the manufacturing workforce (a segment of the production department) is composed of women. Enzyme production is maintained 7 days per week, 24 hours per day in 12 hour work shifts. An individual manufacturing employee will work 36 hours one week and 48 hours on the next consecutive work week. This helps to reduce the problems of shift changes. Manufacturing employees are not permitted to work more than 12 hours in any 24 hour period.

PROCESS DESCRIPTION:
The process surveyed at NBI involves the production of α-amylase using microbial strain of Bacillus licheniformis. This strain of microorganism is non-pathogenic. The manufacture of the industrial enzyme is accomplished in five basic process steps: selection of a microorganism; maintenance of the selected culture; fermentation; concentration and purification of the enzyme product; and standardization of the activity of the enzyme. Neither the selection nor the maintenance of the microorganisms is conducted at NBI.

The selection or screening process for microorganisms determines each culture to be used for a specific enzyme production operation based on their tested ability to produce a commercial quantity of the desired enzyme. Selected cultures must be identified and tested for pathogenicity and their inability to co-produce harmful products or toxins, such as mycotoxins or enterotoxins.

The next process step, maintenance of the selected culture, must ensure that the isolated culture supplied to NBI for large-scale manufacture is a pure, uncontaminated culture medium. This requires that the culture be regrown at intervals. Single colonies are selected for regrowth usually on the basis of culture morphology. The selected culture is grown, harvested, sub-divided, and stored at the appropriate conditions to maintain its viability and purity. Before the culture is used for large-scale fermentation, it is tested to determine whether any desirable characteristics have been lost or undesirable characteristics have appeared. All operations through the first two process steps are conducted in the laboratory using sterile equipment with aseptic transfer.

NBI 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 through a pipe network to the large fermentor (deep-tank reactor vessel). The second phase of the fermentation process is where biosysthesis of the product occurs. 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 coils inside the reactor vessel. The fermentor tank, containing a pre-sterilized nutrient medium, is inoculated with the biomass broth from the seed fermentor. This new broth mixture is aerated, mechanically agitated, and allowed to ferment for continued 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.

The raw materials used to prepare the fermentation nutrient medium are either food grade materials or are tightly controlled to prevent the introduction of contaminants that would inhibit organism growth or enzyme production -- the raw materials must not contain toxic or harmful compounds that could be carried through the process into the final product. Each raw material is contained in a separate tank before being combined in a batching tank to make up the nutrient medium. There is no employee contact with the raw materials after they have been deposited into their individual tanks. Sterilization of the nutrient medium is accomplished with steam in the seed fermentor or large fermentor tank, depending on where the nutrient is to be used.

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 that can be 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 all the fermentor tanks for analysis in the laboratory for microbial morphology, pH, dissolved solids, percent mycellium volume, viscosity, stray organism contamination, etc.

Upon completion of the fermenting cycle, the broth is cooled and piped to a refrigerated holding tank, where agitation is maintained, to await the concentration and purification processing step. Filter aids, pH adjusters, preservatives, etc. are subsequently added to the slurry as a pretreatment to the processing operation. The broth is pumped to a rotary vacuum drum filter (filter aids are used as a precoat) where a major portion of the suspended solids (mycellium and other solids) are separated from the enzyme liquid. A stellite doctor blade shaves off the filter cake and a fraction of the filter aid material. The sludge from the mycellium is steam sterilized and diluted, it is then applied to land surrounding the plant, owned by NBI, as fertilizer for hay crops. Waste water, water used as a liquid wash for process operations, from the plant is perfused through a primary treatment system (activated sludge digestion) to reduce the BOD (Biochemical Oxygen Demand) and this treated water is then used to spray irrigate the hay fields. Further concentration and purification of the enzyme will be accomplished utilizing a vacuum evaporator, ultrafiltrator, and bacterial filter. During this process step, samples are periodically extracted and analyzed for enzyme activity and other properties. Tight controls are necessary to ensure the process is economic and that the final enzyme product will be of food grade quality where applicable.

The final step in the NBI enzyme manufacturing process will be to standardize the activity of the purified enzyme concentrate. This is accomplished by simply blending the enzyme with inert, food grade ingredients. The final product is then packaged in structurally and chemically appropriate containers or drums.

POTENTIAL HAZARDS:
The potential for exposure to hazards in the occupational environment within the fermentation industry in general 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 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 potential health risks that they may pose to the exposed worker. As indicated, the microorganism utilized in the process surveyed at NBI (Bacillus licheniformis) is a non-pathogen. However, increasing attention is being focused upon the potential for immunologic response, after repeated inhalation, to a variety of 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.

Filter aids, such as diatomaceous earth (amorphous silica), are used in the concentration and purification processing step. 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. Prolonged inhalation of calcined diatomaceous earth may cause silicosis with scarring of the lungs, cough, and shortness of breath. The current OSHA standard for amorphous silica is the quotient of 30 mg/m^3 divided by the percent of silica present. The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a maximum exposure of 1.5 mg/m^3 of respirable amorphous silica over an eight hour work shift.

Acids and bases are used to adjust pH levels of biomass broth mixtures or concentrated enzyme liquids throughout the enzyme production process; both will cause burns. Depending on 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 be primary irritants of 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 NBI, 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.

MEASUREMENT OF CONTROL PARAMETERS

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 clean room, incubation room, seed tank, fermentor tank, rotary vacuum drum filter, and in other areas believed to approximate 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

five day period to detect day-to-day variability, if any. Sample times varied from 20 minutes down to 2 $^{1}/_{2}$ minutes depending on the sample location. For example, a sampling time of 20 minutes was used in areas where microbial concentrations (in the laboratory) are expected to be low and a 2 $^{1}/_{2}$ minute sampling time was used in areas of high microbial concentration (around filtering 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 -- non-respirable particles are collected on the top stage, respirable particles are collected on the bottom stage.

Analysis of the viable samples was conducted on-site by a CDC microbiologist and a NIOSH biologist. The primary goal of the microbiological analysis was to determine the numbers of the plant 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.[8] 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 control samples to help ascertain the degree of microorganism release from manufacturing processes.

Enzyme Sampling

Environmental monitoring of the airborne enzyme concentration were conducted using General Metalworks 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 enzyme aerosol release. Locations for the high-volume samplers include the fermentor, rotary vacuum drum filter, aging tanks, weigh station, and dump station. Samples were collected for eight hour workshifts over a four day period. Analysis of the enzyme samples was conducted on-site by a NIOSH chemist according to a NBI α-amylase enzyme activity method.

The 8" x 10" glass fiber filters were weighed before sampling on a Mettler AE 163 balance to 0.01 mg. The instrumental precision for one sitting is 0.01 mg. The sensitivity of the analytical method used to detect α-amylase on the filters proved to be inadequate for the samples collected.

Total Dust Sampling

Total dust samples were 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 eight

hour workshifts over a four day period. The pumps were calibrated prior to the field survey. The PVC filters were pre-weighed in the NBI laboratory (on a Mettler AE 163 balance to 0.01 mg) 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 is reported in the appendix in Table II and summarized in Table III. The classification of a background location was based on the assumption that uncontrollable environmental factors (eg. climatic conditions, surrounding traffic, etc.) had the only significant effect on microbial concentrations. Effects on background locations from plant unit processes was assumed to negligible. The results were assumed to be normally distributed. Viable samples collected from background locations ranged from 120.8 CFU/m^3 for the outside samples to 271.2 CFU/m^3 around the aging tanks. Viable samples collected around selected unit processes ranged from 3.2 CFU/m^3 in the clean room to 705.7 CFU/m^3 at the sample port. The only unit process sample locations statistically different from background concentrations were the sample port and the fermentor tank agitator shaft. The number of the production strain identified at the sample port was minimal. The production strain could not be identified on any of the fermentor tank agitator shaft samples. All samples were blank corrected.

Results of the samples collected with the high-volume air sampler are reported in Table IV. Total dust levels ranged from 0.07 mg/m^3 at the fermentor tank agitator shaft to 0.22 mg/m^3 at the weighing station. Due to complications with the enzyme analytical method enzyme results are unavailable. These complications included an analytical method lacking the desired sensitivity and the degradation of the enzyme molecule caused by the airflow (through the filter) of the sampling instrument.

V. CONTROL TECHNOLOGY

INTRODUCTION - 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. The application of these principles are discussed below.

ENGINEERING CONTROLS

NBI's overall process technology is recent, within the last three years, and therefore relatively advanced. The majority of the large-scale process operations are either controlled or monitored by a computer system which is centrally located in a "control room" within the production building. This "automation" aids in limiting direct employee involvement, and therefore potential hazard exposure or contact, with the process operations. The control room was used as a background concentration and viable samples indicated a level of 271.2 CFU/m^3 with a standard deviation of 79.2. The production strain was identified on 3% of the sample plates.

The enzyme 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 extremely 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, is minimal other than for equipment maintenance or manual broth sample extraction.

Laboratory Process Step:
There are possible emission sources of the production microorganism, Bacillus licheniformis (B1), during the laboratory process step but these sources would be at very low levels due to the small quantity of the microorganism being used. Emissions in the laboratory room were only possible during biochemical analysis of broth samples from the seed and fermentor tanks. General work practices of the lab workers constituted the greatest determinant of viable emissions. The laboratory air quality was controlled with the building ventilation (heating and cooling) system. Fume hoods were accessible in the laboratory for wet chemistry work. A biological safety cabinet (equipped with a UV light inside the hood) was available in the room adjacent to the laboratory.

Possible emissions sites were also observed in the clean room -- during transfer of the B1 cultures from vial to test tube, test tube to flask, and flask to inoculating devices. The clean room contains a horizontal laminar flow hood which purifies recirculated air with a High Efficiency Particulate Air (HEPA) filter. The hood is designed to pass purified air over the work zone, towards the lab technician, to protect the microbial cultures. As a consequence of the airflow directed away from the hood, possible microbial emissions are introduced into the technicians breathing zone. However, the large volume of air recirculated by the hood effectively reduces the concentration of any microbial emissions by diluting the air. The microbial level in the clean room was 3.2 CFU/m^3 with a standard deviation of 4.4. The production strain was identified on 33% of the sample plates.

Flasks inoculated with the B1 culture are transferred to an incubation room adjacent to the clean room. The incubation room is kept at a constant temperature and humidity for proper propagation of the microbial culture. The flasks are sealed with a cotton gauze stopper. The microbial level in the incubation room was 220.8 CFU/m^3 with a standard deviation of 176.7. The production strain could not be located on any of the sample plates.

The microbial culture is manually moved from the laboratory to the seed tank in a sterile, stainless steel inoculating device which serves as containment device during the transfer. The inoculating device is then connected to a steam sealed line on the seed tank and the microbial culture is released into the seed tank. The inoculating device is returned to the laboratory and autoclaved. It was observed that transfer of the microbial culture from the flask to the inoculating device periodically occurred in the hall outside the clean room. The microbial level in this hallway was 308.8 CFU/m^3 with a standard deviation of 174.5. The production strain could not be located on any of the sample plates.

Fermentation Process Step:
Minor potential for release of aerosolized viables and/or enzymes exists at certain sites around the seed and fermentor tanks. These sites include the broth sampling ports, agitator shafts, and exhaust ducts for the seed and fermentor tank off-gases. Broth sampling at the seed and 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. After sampling the valve is shut off, the steam is increased to clear the valve of remaining contaminants. The steam release observed was a completely opened valve which aerosolized any microoganisms remaining in the valve. Proper company procedure is to open the steam valve only enough to gently wash any remaining microorganisms into a catch basin. No engineering controls or protective equipment was used during sampling. The sampling procedure occurred once per day and was the same for the seed tank and the fermentor tank. The microbial level around the sampling port during manual broth sampling was 705.7 CFU/m^3 with a standard deviation of 266.6. The production strain was identified on 17% of the sample plates.

The agitator shaft of the seed and fermentor tank is a double mechanical steam seal. Sampling around the fermentor tank agitator shaft indicated a microbial level of 285.2 CFU/m^3 with a standard deviation of 33.3. The total dust level at this location was 0.07 mg/m^3 with a standard deviation of 0.02. Sampling around the seed tank agitator shaft indicated a microbial level of 326.9 CFU/m^3 with a standard deviation of 50.8. The production strain could not be located on any of the sample plates at these two locations.

The off-gases from the seed and fermentor tanks were ducted to a scrubber and then to an ozone treatment device to eliminate odors. Plant representatives claimed that in addition to the elimination of odors the ozone treatment effectively decontaminated the outgoing air of viable microbes. Viable samples were not conducted due to the inaccessability of an adequate sampling location.

All bag dumping stations, which includes the dumping of raw materials, acids, bases, and diatomaceous earth into their separate container vessels, are controlled with local exhaust ventilation hoods. The ducts for each hood are equipped with manually adjustable dampers which were designed to be closed when the hood is not in use. General work practices of the operators constituted the greatest determinant of exposures. For example, proper company procedure for the disposal of empty bags is to deposit the empty bags into a bag compaction unit which then moves compacted bags into a plastic sack. This sack is then closed with a minimum of exposure to the operator. However, when the plastic sack became full operators neglected to remove and close the sack. Consequently, the sack would fall off of the compaction unit and the compacted bags would then be deposited on the floor. The workers then disposed of the full plastic sack and the compacted bags separately into a dumpster. One bag compaction unit was equipped with local exhaust ventilation. The total dust level at this location was 0.11 mg/m^3. The total dust level at a weigh station on the other side of the materials handling room was 0.22 mg/m^3 with a standard deviation of 0.11.

Recovery Process Step:
After the fermentation cycle, the microbial/enzyme broth is transferred through pipe to a holding tank to await concentration and purification. Agitation is maintained in the holding tank but not aeration. The broth is then separated by a rotary vacuum drum filter. The drum filter has a local exhaust ventilation hood on one side which is exhausted to the building ventilation system. Samples collected around the drum filter indicated an average microbial concentration of 345.1 CFU/m^3 with a standard deviation of 153.8. This level was compared to a background level across the room next to the aging tanks (location average was 531.6 CFU/m^3 with a standard deviation of 188.1) and was not statistically different. The production strain was identified on 22% of the sample plates. The total dust level at this location was 0.12 mg/m^3 with a standard deviation of 0.02.

The low microbial concentrations and non-existence of the production strain around the rotary vacuum drum filter could have a number of possible explanations. First, the stress from the solid-liquid separation of the drum filter may have weakened production cells to a state of non-viability. Second, asphyxiation (caused by the lack of aeration) may have occurred to

those cells resident in the holding tank prior to separation. In addition, the holding tank is refrigerated which could have effected the viability of the cells. The debilitation or inadvertent destruction of the production microorganisms during separation can be an effective control in reducing emissions. Third, the local exhaust hood in combination with the adherence of cells to the filter (vacuum generated) effectively minimized the potential emissions. The low microbial concentration also indicates the effective sterilization by steam infusion immediately following separation.

WORK PRACTICES

NBI requires that their employees maintain a clean occupational environment; not only to ensure that the final product remains free of contaminants, but also to prevent the workers from being unnecessarily exposed to hazardous agents or conditions. Good housekeeping is promoted as part of this "clean" attitude in the safety procedures. In addition, a spill control procedure has been outlined and implemented within the Manufacturing Area. The procedures attempt to address and resolve two problems; one, control of the spill and clean-up of the spilled material, and two, disposal of the spilled material and its effect on the NBI waste treatment system. The procedures include spills pertaining to food grade ingredients or chemicals, salts, bases, acids, oils and refrigerants, and fuel oils. Employees are expected to include themselves as part of this clean work environment. Clean clothes, provided and cleaned by NBI, are required everyday. Showers are also required at the end of every work day -- lockers are also provided for each employee.

NBI employs a computerized preventative maintenance program as part of their "good" work practice regime. Weekly printouts are provided by the computer detailing the equipment and/or instruments in need of routine maintenance. There is also a monthly, quarterly, or elapsed time, dependent upon the degree of bearing usage, vibration analysis conducted on all bearings.

MONITORING

The environmental health program in effect at the Franklinton plant is monitored by the Quality Control Manager of NBI. Although NBI does not employ a full-time industrial hygienist at the plant, there is a corporate industrial hygienist available on a consulting basis from Novo Laboratories, Inc., Wilton, Connecticut. As part of this program, routine workplace concentration monitoring is conducted for active aerosolized liquid enzymes. Samples are taken at six different monitoring locations utilizing a Galley high-volume sampler. All assays are accomplished in-house at the Franklinton plant laboratory.

NBI implements a relatively complete medical/biological examination and monitoring program. Pre-screening employee physicals are conducted including a complete allergy battery and interpretation. Blood samples are taken annually from all employees for Radioallergosorbent (RAST) Tests to determine whether antibodies are being produced to specific antigen-producing compounds to which they may be exposed. Exposure records are maintained for each employee. Annual audiometric tests are conducted in order to monitor employees' hearing ability and to note any changes or deterioration that may

occur. Annual physical examinations for employees include urine specimens, pulmonary function, chart eye checks, ear checks for wax accumulation, tetanus toxoid or booster (every 5 years), and a review of employees' previous physical examination records. A heavy emphasis is placed upon the respiratory evaluation section of the annual physicals. There are no medical practitioners (doctors, nurses, etc.) on call at the plant during normal working hours, however, there are two local physicians used for physicals and medical emergencies. In addition, there is a rescue squad available 3 miles from the plant complex to the west in Franklinton and a hospital located 6 miles to the east in Louisburg.

PERSONAL PROTECTION

NBI's safety program and operations are guided by a Safety Committee composed of a chairman and two members, one salaried and one hourly, from each of the following Departments; Maintenance, Manufacturing, Farm, and Laboratory. In addition a member of the Personnel Department serves on the Committee. The chairmanship rotates between departments. This committee conducts monthly meetings and makes quarterly safety inspections of all facilities. Quarterly safety lectures for the workers are maintained with additional programs in emergency training and Cardio Pulmonary Resuscitation (CPR). Safety problems are considered a priority. All accidents are documented. NBI states they have had 3 years with no lost-time accidents.

Personal protection requirements are part of the NBI safety procedures. Safety glasses are required to be worn at all times except when face shields or goggles are required. Safety shoes are required to be worn at all times except for "walk-throughs." Ear protection is required to be worn while working in the evaporator and utility rooms. Disposable dust respirators are required to be worn in all bag emptying processes and areas where enzyme contamination is suspected. Disposable dust respirators are also required when repairing the internal portions of these units where exposure may be expected -- this includes the filter changing operation in the heating and ventilation units. Acid goggles, rubber gloves, and an apron is required to be worn while transporting or handling acids and caustics. A respirator (Willson canister type - Type H-3), rubber gloves, and a rain suit are required to be worn whenever a worker is handling formaldehyde.

NBI employs a company procedure for entering a deep-tank reactor vessel. These procedures include a second person as an observer, continuous fresh air replenishment inside the tank during the complete operation, a safety harness attached to a mechanical lifting device, and a mechanical/electrical lockout procedure.

VI. DISCUSSION

Viable sample concentrations around selected unit processes were compared (using the t-statistic for comparing two means) to background concentrations to ascertain the degree of containment of those processes.[10] The results indicate an effective system of control measures. These control measures are, in part, responsible for the limited potential for exposure to the microorganisms, process chemical intermediates, and/or the biological

products of the enzyme operation. Total microbial levels were elevated in the warm, moist environments around the fermentor tank agitator shaft and the sample port, but the production strain was only minimally present or not present at all on the agar plates. Work practices of the operators or technicians can be a determining factor in the degree of exposure for a number of unit operations (eg. dumping stations and sampling port). Proper company procedure for these operations appears to be adequate to minimize worker exposures -- but these procedures can only be effective if practiced by the operator.

VII. REFERENCES

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TABLE I. Equipment Used on Field Survey

Item	Model	
Automatic balance	Mettler AE 163	gravimetric analysis
Automatic psychrometer	Vista Scientific Corporation	temperature and humidity
Colony Counter	New Brunswick Scientific	colony counts and identification
High-volume air sampler	General Metal Works	enzyme and total dust sampling
Hot-wire anemometer	Kurz	air velocity
Personal sampling pump	Dupont 2500	total dust sampling
Personal sampling pump	Dupont P-200	acetone sampling
Smoke tubes	Draeger	air flow patterns
Viable cascade impactor	Andersen 2-stage	microbial air sampling

TABLE II. Viable Sampling Results

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Rotary Vacuum Drum Filter	09-Sep	1000	Non-resp	1307	20	35	84	58%	148.41		
Rotary Vacuum Drum Filter	09-Sep	1001	Resp	1307	20	49					
Rotary Vacuum Drum Filter	09-Sep	1002	Non-resp	1307	20	54	135	60%	236.15		
Rotary Vacuum Drum Filter	09-Sep	1003	Resp	1307	20	81					
Rotary Vacuum Drum Filter	09-Sep	1004	Non-resp	1334	15	28	81	65%	190.81		
Rotary Vacuum Drum Filter	09-Sep	1005	Resp	1334	15	53					
Rotary Vacuum Drum Filter	09-Sep	1007	Non-resp	1334	15	64	115	44%	268.22		
Rotary Vacuum Drum Filter	09-Sep	1006	Resp	1334	15	51					
Rotary Vacuum Drum Filter	09-Sep	1008	Non-resp	1356	10	15	34	56%	120.14		
Rotary Vacuum Drum Filter	09-Sep	1009	Resp	1356	10	19					
Rotary Vacuum Drum Filter	09-Sep	1010	Non-resp	1356	10	31	50	38%	174.93		
Rotary Vacuum Drum Filter	09-Sep	1011	Resp	1356	10	19					
Rotary Vacuum Drum Filter	09-Sep	1016	Non-resp	1454	10	11	23	52%	81.27		
Rotary Vacuum Drum Filter	09-Sep	1017	Resp	1454	10	12					
Rotary Vacuum Drum Filter	09-Sep	1018	Non-resp	1454	10	6	19	68%	66.47		
Rotary Vacuum Drum Filter	09-Sep	1019	Resp	1454	10	13					
Rotary Vacuum Drum Filter	09-Sep	1020	Non-resp	1514	10	66	101	35%	356.89		
Rotary Vacuum Drum Filter	09-Sep	1021	Resp	1514	10	35					
Rotary Vacuum Drum Filter	09-Sep	1022	Non-resp	1514	10	27	60	55%	209.91		
Rotary Vacuum Drum Filter	09-Sep	1023	Resp	1514	10	33					
Rotary Vacuum Drum Filter	09-Sep	1024	Non-resp	1528	10	22	41	46%	144.88		
Rotary Vacuum Drum Filter	09-Sep	1025	Resp	1528	10	19					
Rotary Vacuum Drum Filter	09-Sep	1026	Non-resp	1528	10	28	46	39%	160.93		
Rotary Vacuum Drum Filter	09-Sep	1027	Resp	1528	10	18					
Rotary Vacuum Drum Filter	09-Sep	1028	Non-resp	1545	10	6	23	74%	81.27		
Rotary Vacuum Drum Filter	09-Sep	1029	Resp	1545	10	17					
Rotary Vacuum Drum Filter	09-Sep	1030	Non-resp	1545	10	24	45	47%	157.44		
Rotary Vacuum Drum Filter	09-Sep	1031	Resp	1545	10	21					
Rotary Vacuum Drum Filter	09-Sep	1032	Non-resp	1601	10	23	44	48%	155.48		

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Rotary Vacuum Drum Filter	09-Sep	1033	Resp	1601	10	21					
Rotary Vacuum Drum Filter	09-Sep	1034	Non-resp	1601	10	53	89	40%	311.37		
Rotary Vacuum Drum Filter	09-Sep	1035	Resp	1601	10	36					
Rotary Vacuum Drum Filter	09-Sep	1036	Non-resp	1617	10	32	53	40%	187.28		
Rotary Vacuum Drum Filter	09-Sep	1037	Resp	1617	10	21					
Rotary Vacuum Drum Filter	09-Sep	1038	Non-resp	1617	10	50	84	40%	293.88		
Rotary Vacuum Drum Filter	09-Sep	1039	Resp	1617	10	34					
Background - paint shed	09-Sep	2000	Non-resp	1249	20	32	51	37%	90.11		
Background - paint shed	09-Sep	2001	Resp	1249	20	19					
Background - paint shed	09-Sep	2002	Non-resp	1249	20	28	41	32%	72.44		
Background - paint shed	09-Sep	2003	Resp	1249	20	13					
Background - paint shed	09-Sep	2004	Non-resp	1317	20	88	101	13%	178.45		
Background - paint shed	09-Sep	2005	Resp	1317	20	13					
Background - paint shed	09-Sep	2006	Non-resp	1317	20	20	29	31%	51.24		
Background - paint shed	09-Sep	2007	Resp	1317	20	9					
Background - paint shed	09-Sep	2008	Non-resp	1343	15	8	14	43%	32.98		
Background - paint shed	09-Sep	2009	Resp	1343	15	6					
Background - paint shed	09-Sep	2010	Non-resp	1343	15	11	19	42%	44.76		
Background - paint shed	09-Sep	2011	Resp	1343	15	8					
Background - paint shed	09-Sep	2016	Non-resp	1451	10	1	1	0%	3.53		
Background - paint shed	09-Sep	2017	Resp	1451	10	0					
Background - paint shed	09-Sep	2018	Non-resp	1451	10	5	5	0%	17.67		
Background - paint shed	09-Sep	2019	Resp	1451	10	0					
Background - paint shed	09-Sep	2020	Non-resp	1508	9	16	16	0%	62.82		
Background - paint shed	09-Sep	2021	Resp	1508	9	0					
Background - paint shed	09-Sep	2022	Non-resp	1508	9	10	11	9%	43.19		
Background - paint shed	09-Sep	2023	Resp	1508	9	1					
Sample Port - fermentor tank	10-Sep	2024	Non-resp	0501	6	24	115	79%	677.27		
Sample Port - fermentor tank	10-Sep	2025	Resp	0501	6	91					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Sample Port - fermentor tank	10-Sep	2026	Non-resp	0501	6	19	64	70%	376.91		
Sample Port - fermentor tank	10-Sep	2027	Resp	0501	6	45					
Sample Port - fermentor tank	10-Sep	2028	Non-resp	0501	6	22	57	61%	335.69		
Sample Port - fermentor tank	10-Sep	2029	Resp	0501	6	35					
Sample Port - fermentor tank	10-Sep	2030	Non-resp	0521	6	39	164	76%	965.84	1.0	1.00
Sample Port - fermentor tank	10-Sep	2031	Resp	0521	6	125					
Sample Port - fermentor tank	10-Sep	2032	Non-resp	0521	6	35	167	79%	983.51		
Sample Port - fermentor tank	10-Sep	2033	Resp	0521	6	132					
Sample Port - fermentor tank	10-Sep	2034	Non-resp	0521	6	16	152	89%	895.17		
Sample Port - fermentor tank	10-Sep	2035	Resp	0521	6	136					
Control Room	10-Sep	3000	Non-resp	0700	20	174	249	30%	439.93		
Control Room	10-Sep	3001	Resp	0700	20	75					
Control Room	10-Sep	3002	Non-resp	0724	15	178	261	32%	614.84		
Control Room	10-Sep	3003	Resp	0724	15	83					
Control Room	10-Sep	3004	Non-resp	0745	15	203	294	31%	692.58		
Control Room	10-Sep	3005	Resp	0745	15	91					
Control Room	10-Sep	3006	Non-resp	0805	15	93	145	36%	341.58		
Control Room	10-Sep	3007	Resp	0805	15	52					
Control Room	10-Sep	3008	Non-resp	0825	15	56	84	33%	197.88		
Control Room	10-Sep	3009	Resp	0825	15	28					
Control Room	10-Sep	3012	Non-resp	0905	20	116	166	30%	293.29		
Control Room	10-Sep	3013	Resp	0905	20	50					
Control Room	10-Sep	3014	Non-resp	0930	15	86	112	23%	263.84		
Control Room	10-Sep	3015	Resp	0930	15	26					
Control Room	10-Sep	3016	Non-resp	0950	15	58	92	37%	216.73		
Control Room	10-Sep	3017	Resp	0950	15	34					
Background - paint shed	10-Sep	3020	Non-resp	1237	30	114	231	51%	272.08		
Background - paint shed	10-Sep	3021	Resp	1237	30	117					
Background - paint shed	10-Sep	3018	Non-resp	1315	15	13	20	35%	47.11		

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Background - paint shed	10-Sep	3019	Resp	1315	15	7					
Background - paint shed	10-Sep	3022	Non-resp	1334	15	44	70	37%	164.90		
Background - paint shed	10-Sep	3023	Resp	1334	15	26					
Background - paint shed	10-Sep	3024	Non-resp	1353	10	28	69	59%	243.82		
Background - paint shed	10-Sep	3025	Resp	1353	10	41					
Fermentor Agitator Shafts - F and E	10-Sep	4000	Non-resp	0712	10	24	58	59%	204.95		
Fermentor Agitator Shafts - F and E	10-Sep	4001	Resp	0712	10	34					
Fermentor Agitator Shafts - F and E	10-Sep	4002	Non-resp	0712	10	22	58	62%	204.95		
Fermentor Agitator Shafts - F and E	10-Sep	4003	Resp	0712	10	36					
Fermentor Agitator Shafts - F and E	10-Sep	4004	Non-resp	0730	10	13	42	69%	148.41		
Fermentor Agitator Shafts - F and E	10-Sep	4005	Resp	0730	10	29					
Fermentor Agitator Shafts - F and E	10-Sep	4006	Non-resp	0730	10	31	78	60%	275.62		
Fermentor Agitator Shafts - F and E	10-Sep	4007	Resp	0730	10	47					
Fermentor Agitator Shafts - F and E	10-Sep	4008	Non-resp	0827	10	0	11	100%	38.87		
Fermentor Agitator Shafts - F and E	10-Sep	4009	Resp	0827	10	11					
Fermentor Agitator Shafts - F and E	10-Sep	4010	Non-resp	0827	10	7	20	65%	70.67		
Fermentor Agitator Shafts - F and E	10-Sep	4011	Resp	0827	10	13					
Fermentor Agitator Shafts - F and E	10-Sep	4012	Non-resp	0838	10	25	31	19%	109.54		
Fermentor Agitator Shafts - F and E	10-Sep	4013	Resp	0838	10	6					
Fermentor Agitator Shafts - F and E	10-Sep	4014	Non-resp	0838	10	9	21	57%	74.20		
Fermentor Agitator Shafts - F and E	10-Sep	4015	Resp	0838	10	12					
Fermentor Agitator Shafts - F and E	10-Sep	4016	Non-resp	0850	15	64	90	29%	212.01		
Fermentor Agitator Shafts - F and E	10-Sep	4017	Resp	0850	15	26					
Fermentor Agitator Shafts - F and E	10-Sep	4018	Non-resp	0850	15	18	40	55%	94.23		
Fermentor Agitator Shafts - F and E	10-Sep	4019	Resp	0850	15	22					
Fermentor Agitator Shafts - F and E	10-Sep	4024	Non-resp	0906	10	17	33	48%	116.61		
Fermentor Agitator Shafts - F and E	10-Sep	4025	Resp	0906	10	16					
Fermentor Agitator Shafts - F and E	10-Sep	4026	Non-resp	0906	10	5	28	82%	98.94		
Fermentor Agitator Shafts - F and E	10-Sep	4027	Resp	0906	10	23					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Fermentor Agitator Shafts - F and E	10-Sep	4028	Non-resp	0917	10	28	40	30%	141.34		
Fermentor Agitator Shafts - F and E	10-Sep	4029	Resp	0917	10	12					
Fermentor Agitator Shafts - F and E	10-Sep	4030	Non-resp	0917	10	34	64	47%	226.15		
Fermentor Agitator Shafts - F and E	10-Sep	4031	Resp	0917	10	30					
Fermentor Agitator Shafts - F and E	10-Sep	4032	Non-resp	1103	10	19	45	58%	159.01		
Fermentor Agitator Shafts - F and E	10-Sep	4033	Resp	1103	10	26					
Fermentor Agitator Shafts - F and E	10-Sep	4034	Non-resp	1103	10	3	28	89%	98.94		
Fermentor Agitator Shafts - F and E	10-Sep	4035	Resp	1103	10	25					
Fermentor Agitator Shafts - F and E	10-Sep	4036	Non-resp	1117	15	2	23	91%	54.18		
Fermentor Agitator Shafts - F and E	10-Sep	4037	Resp	1117	15	21					
Fermentor Agitator Shafts - F and E	10-Sep	4038	Non-resp	1117	15	7	31	77%	73.03		
Fermentor Agitator Shafts - F and E	10-Sep	4039	Resp	1117	15	24					
Fermentor Agitator Shafts - F and E	10-Sep	4040	Non-resp	1240	10	64	104	38%	367.49		
Fermentor Agitator Shafts - F and E	10-Sep	4041	Resp	1240	10	40					
Fermentor Agitator Shafts - F and E	10-Sep	4042	Non-resp	1240	10	55	92	40%	325.09		
Fermentor Agitator Shafts - F and E	10-Sep	4043	Resp	1240	10	37					
Fermentor Agitator Shafts - F and E	10-Sep	4044	Non-resp	1251	15	229	431	47%	1015.31		
Fermentor Agitator Shafts - F and E	10-Sep	4045	Resp	1251	15	202					
Fermentor Agitator Shafts - F and E	10-Sep	4046	Non-resp	1251	15	218	393	45%	925.80		
Fermentor Agitator Shafts - F and E	10-Sep	4047	Resp	1251	15	175					
Fermentor Agitator Shafts - F and E	10-Sep	4048	Non-resp	1308	10	71	146	51%	515.90		
Fermentor Agitator Shafts - F and E	10-Sep	4049	Resp	1308	10	75					
Fermentor Agitator Shafts - F and E	10-Sep	4050	Non-resp	1308	10	188	276	32%	975.27		
Fermentor Agitator Shafts - F and E	10-Sep	4051	Resp	1308	10	88					
Fermentor Agitator Shafts - F and E	10-Sep	4052	Non-resp	1322	12	34	75	55%	220.85		
Fermentor Agitator Shafts - F and E	10-Sep	4053	Resp	1322	12	41					
Fermentor Agitator Shafts - F and E	10-Sep	4054	Non-resp	1319	15	25	65	62%	153.12		
Fermentor Agitator Shafts - F and E	10-Sep	4055	Resp	1319	15	40					
Fermentor Agitator Shafts - F and E	10-Sep	4060	Non-resp	1334	10	10	23	57%	81.27		

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Fermentor Agitator Shafts - F and E	10-Sep	4061	Resp	1334	10	13					
Fermentor Agitator Shafts - F and E	10-Sep	4062	Non-resp	1334	10	9	20	55%	70.67		
Fermentor Agitator Shafts - F and E	10-Sep	4063	Resp	1334	10	11					
Clean Room	10-Sep	5000	Non-resp	1038	15	0	0		0.00		
Clean Room	10-Sep	5001	Resp	1038	15	0					
Clean Room	10-Sep	5002	Non-resp	1038	15	0	0		0.00		
Clean Room	10-Sep	5003	Resp	1038	15	0					
Clean Room	10-Sep	5004	Non-resp	1105	15	0	0		0.00		
Clean Room	10-Sep	5005	Resp	1105	15	0				1.0	1.00
Clean Room	10-Sep	5006	Non-resp	1105	15	0				1.0	1.00
Clean Room	10-Sep	5007	Resp	1105	15						
Clean Room	10-Sep	7000	Non-resp	1529	20	0	2	100%	3.53		
Clean Room	10-Sep	7001	Resp	1529	20	2					
Clean Room	10-Sep	7002	Non-resp	1553	20	0	7	100%	12.37		
Clean Room	10-Sep	7003	Resp	1553	20	7					
Clean Room	10-Sep	7004	Non-resp	1617	20	1	2	50%	3.53		
Clean Room	10-Sep	7005	Resp	1617	20	1					
Background - paint shed north	11-Sep	c3026	Non-resp	0810	15	20	92	78%	216.73		
Background - paint shed north	11-Sep	c3027	Resp	0810	15	72					
Background - paint shed north	11-Sep	c3028	Non-resp	0831	15	151	271	44%	638.40		
Background - paint shed north	11-Sep	c3029	Resp	0831	15	120					
Background - paint shed north	11-Sep	c3030	Non-resp	0850	15	111	254	56%	598.35		
Background - paint shed north	11-Sep	c3031	Resp	0850	15	143					
Background - paint shed north	11-Sep	c3032	Non-resp	0910	15	59	258	77%	607.77		
Background - paint shed north	11-Sep	c3033	Resp	0910	15	199					
Background - paint shed north	11-Sep	c3034	Non-resp	0930	15	36	154	77%	362.78		
Background - paint shed north	11-Sep	c3035	Resp	0930	15	118					
Background - paint shed north	11-Sep	c3038	Non-resp	0956	20	125	252	50%	445.23		
Background - paint shed north	11-Sep	c3039	Resp	0956	20	127					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Background - filter press in building	11-Sep	c3040	Non-resp	1028	15	126	283	55%	666.67		
Background - filter press in building	11-Sep	c3041	Resp	1028	15	157					
Background - filter press in building	11-Sep	c3042	Non-resp	1048	15	50	214	77%	504.12		
Background - filter press in building	11-Sep	c3043	Resp	1048	15	164					
Background - filter press in building	11-Sep	c3044	Non-resp	1107	15	54	248	78%	584.22		
Background - filter press in building	11-Sep	c3045	Resp	1107	15	194					
Background - filter press in building	11-Sep	c3046	Non-resp	1127	15	53	147	64%	346.29		
Background - filter press in building	11-Sep	c3047	Resp	1127	15	94					
Background - filter press in building	11-Sep	c3050	Non-resp	1259	15	7	15	53%	35.34		
Background - filter press in building	11-Sep	c3051	Resp	1259	15	8					
Background - filter press in building	11-Sep	c3054	Non-resp	1403	15	22	67	67%	157.83		
Background - filter press in building	11-Sep	c3055	Resp	1403	15	45					
Incubation Room	11-Sep	3060	Non-resp	1443	20	17	39	56%	68.90		
Incubation Room	11-Sep	3061	Resp	1443	20	22					
Incubation Room	11-Sep	3062	Non-resp	1507	20	4	18	78%	31.80		
Incubation Room	11-Sep	c3063	Resp	1507	20	14					
Incubation Room	11-Sep	c3064	Non-resp	1533	20	8	18	56%	31.80		
Incubation Room	11-Sep	c3065	Resp	1533	20	10					
Hall - outside incubation room	11-Sep	3066	Non-resp	1558	20	50	76	34%	134.28		
Hall - outside incubation room	11-Sep	3067	Resp	1558	20	26					
Fermentor Agitator Shafts - F and E	11-Sep	c4064	Non-resp	1241	15	56	194	71%	457.01		
Fermentor Agitator Shafts - F and E	11-Sep	c4065	Resp	1241	15	138					
Fermentor Agitator Shafts - F and E	11-Sep	c4066	Non-resp	1241	15	57	173	67%	407.54		
Fermentor Agitator Shafts - F and E	11-Sep	c4067	Resp	1241	15	116					
Fermentor Agitator Shafts - F and E	11-Sep	c4068	Non-resp	1257	20	50	203	75%	358.66		
Fermentor Agitator Shafts - F and E	11-Sep	c4069	Resp	1257	20	153					
Fermentor Agitator Shafts - F and E	11-Sep	c4070	Non-resp	1257	20	33	191	83%	337.46		
Fermentor Agitator Shafts - F and E	11-Sep	c4071	Resp	1257	20	158					
Fermentor Agitator Shafts - F and E	11-Sep	c4072	Non-resp	1318	20	65	215	70%	379.86		

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Fermentor Agitator Shafts - F and E	11-Sep	c4073	Resp	1318	20	150					
Fermentor Agitator Shafts - F and E	11-Sep	c4074	Non-resp	1318	20	49	153	68%	270.32		
Fermentor Agitator Shafts - F and E	11-Sep	c4075	Resp	1318	20	104					
Fermentor Agitator Shafts - F and E	11-Sep	c4076	Non-resp	1339	20	60	204	71%	360.42		
Fermentor Agitator Shafts - F and E	11-Sep	c4077	Resp	1339	20	144					
Fermentor Agitator Shafts - F and E	11-Sep	c4078	Non-resp	1339	20	74	214	65%	378.09		
Fermentor Agitator Shafts - F and E	11-Sep	c4079	Resp	1339	20	140					
Fermentor Agitator Shafts - F and E	11-Sep	c4080	Non-resp	1400	20	34	72	53%	127.21		
Fermentor Agitator Shafts - F and E	11-Sep	c4081	Resp	1400	20	38					
Fermentor Agitator Shafts - F and E	11-Sep	c4082	Non-resp	1400	20	23	61	62%	107.77		
Fermentor Agitator Shafts - F and E	11-Sep	c4083	Resp	1400	20	38					
Seed Fermentor	11-Sep	4500	Non-resp	1513	15	229	302	24%	711.43		
Seed Fermentor	11-Sep	4501	Resp	1513	15	73					
Seed Fermentor	11-Sep	4502	Non-resp	1513	15	254	325	22%	765.61		
Seed Fermentor	11-Sep	4503	Resp	1513	15	71					
Seed Fermentor	11-Sep	4504	Non-resp	1529	15	24	79	70%	186.10		
Seed Fermentor	11-Sep	4505	Resp	1529	15	55					
Seed Fermentor	11-Sep	4506	Non-resp	1529	15	64	158	59%	372.20		
Seed Fermentor	11-Sep	4507	Resp	1529	15	94					
Seed Fermentor	11-Sep	4512	Non-resp	1544	15	27	48	44%	113.07		
Seed Fermentor	11-Sep	4513	Resp	1544	15	21					
Seed Fermentor	11-Sep	4514	Non-resp	1544	15	26	50	48%	117.79		
Seed Fermentor	11-Sep	4515	Resp	1544	15	24					
Control Room	11-Sep	c6024	Non-resp	0948	15	28	46	39%	108.36		
Control Room	11-Sep	c6025	Resp	0948	15	18					
Control Room	11-Sep	c6026	Non-resp	0948	15	29	50	42%	117.79		
Control Room	11-Sep	c6027	Resp	0948	15	21					
Control Room	11-Sep	c6028	Non-resp	1004	20	73	121	40%	213.78		
Control Room	11-Sep	c6029	Resp	1004	20	48					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Control Room	11-Sep	c6030	Non-resp	1004	20	59	120	51%	212.01		
Control Room	11-Sep	c6031	Resp	1004	20	61					
Control Room	11-Sep	c6016	Non-resp	0932	15	49	59	17%	138.99		
Control Room	11-Sep	c6017	Resp	0932	15	10					
Control Room	11-Sep	c6018	Non-resp	0932	15	59	80	26%	188.46		
Control Room	11-Sep	c6019	Resp	0932	15	21					
Control Room	11-Sep	c6008	Non-resp	0854	20	98	147	33%	259.72		
Control Room	11-Sep	c6009	Resp	0854	20	49					
Control Room	11-Sep	c6011	Non-resp	0854	20	100	184	46%	325.09		
Control Room	11-Sep	c6010	Resp	0854	20	84					
Control Room	11-Sep	c6012	Non-resp	0915	15	20	52	62%	122.50		
Control Room	11-Sep	c6013	Resp	0915	15	32					
Control Room	11-Sep	c6014	Non-resp	0915	15	33	66	50%	155.48		
Control Room	11-Sep	c6015	Resp	0915	15	33					
Control Room	11-Sep	c6000	Non-resp	0816	20	64	124	48%	219.08		
Control Room	11-Sep	c6001	Resp	0816	20	60					
Control Room	11-Sep	c6002	Non-resp	0816	20	75	119	37%	210.25		
Control Room	11-Sep	c6003	Resp	0816	20	44					
Control Room	11-Sep	c6004	Non-resp	0837	15	61	110	45%	259.13		
Control Room	11-Sep	c6005	Resp	0837	15	49					
Control Room	11-Sep	c6006	Non-resp	0837	15	54	144	63%	339.22		
Control Room	11-Sep	c6007	Resp	0837	15	90					
Seed Fermentor	12-Sep	4516	Non-resp	0833	15	67	141	52%	332.16		
Seed Fermentor	12-Sep	4517	Resp	0833	15	74					
Seed Fermentor	12-Sep	4518	Non-resp	0833	15	36	90	60%	212.01		
Seed Fermentor	12-Sep	4519	Resp	0833	15	54					
Seed Fermentor	12-Sep	4520	Non-resp	0849	10	34	89	62%	314.49		
Seed Fermentor	12-Sep	4521	Resp	0849	10	55					
Seed Fermentor	12-Sep	4522	Non-resp	0849	10	39	90	57%	318.02		

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Seed Fermentor	12-Sep	4523	Resp	0849	10	51					
Seed Fermentor	12-Sep	4534	Non-resp	0859	15	52	193	73%	454.65		
Seed Fermentor	12-Sep	4525	Resp	0859	15	141					
Seed Fermentor	12-Sep	4526	Non-resp	0859	15	57	187	70%	440.52		
Seed Fermentor	12-Sep	4527	Resp	0859	15	130					
Seed Fermentor	12-Sep	4528	Non-resp	0915	15	49	209	77%	492.34		
Seed Fermentor	12-Sep	4529	Resp	0915	15	160					
Seed Fermentor	12-Sep	4530	Non-resp	0915	15	65	213	69%	501.77		
Seed Fermentor	12-Sep	4531	Resp	0915	15	148					
Seed Fermentor	12-Sep	4536	Non-resp	0930	20	50	141	65%	249.12		
Seed Fermentor	12-Sep	4537	Resp	0930	20	91					
Seed Fermentor	12-Sep	4538	Non-resp	0930	20	39	134	71%	236.75		
Seed Fermentor	12-Sep	4539	Resp	0930	20	95					
Seed Fermentor	12-Sep	4540	Non-resp	0951	15	23	76	70%	179.03		
Seed Fermentor	12-Sep	4541	Resp	0951	15	53					
Seed Fermentor	12-Sep	4542	Non-resp	0951	15	35	70	50%	164.90		
Seed Fermentor	12-Sep	4543	Resp	0951	15	35					
Seed Fermentor	12-Sep	4544	Non-resp	1006	15	21	52	60%	122.50		
Seed Fermentor	12-Sep	4545	Resp	1006	15	31					
Seed Fermentor	12-Sep	4546	Non-resp	1006	15	13	44	70%	103.65		
Seed Fermentor	12-Sep	4547	Resp	1006	15	31					
Seed Fermentor	12-Sep	4548	Non-resp	1022	20	53	112	53%	197.88		
Seed Fermentor	12-Sep	4549	Resp	1022	20	59					
Seed Fermentor	12-Sep	4550	Non-resp	1022	20	34	95	64%	167.84		
Seed Fermentor	12-Sep	4551	Resp	1022	20	61					
Seed Fermentor	12-Sep	4552	Non-resp	1043	15	52	112	54%	263.84		
Seed Fermentor	12-Sep	4553	Resp	1043	15	60					
Seed Fermentor	12-Sep	4554	Non-resp	1043	15	30	93	68%	219.08		
Seed Fermentor	12-Sep	4555	Resp	1043	15	63					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Rotary Vacuum Drum Filter	12-Sep	1500	Non-resp	1245	15	24	57	58%	134.28		
Rotary Vacuum Drum Filter	12-Sep	1501	Resp	1245	15	33					
Rotary Vacuum Drum Filter	12-Sep	1502	Non-resp	1245	15	23	28	18%	65.96		
Rotary Vacuum Drum Filter	12-Sep	1503	Resp	1245	15	5					
Rotary Vacuum Drum Filter	12-Sep	1504	Non-resp	1301	20	14	84	83%	148.41		
Rotary Vacuum Drum Filter	12-Sep	1505	Resp	1301	20	70					
Rotary Vacuum Drum Filter	12-Sep	1506	Non-resp	1301	20	26	94	72%	166.08		
Rotary Vacuum Drum Filter	12-Sep	1507	Resp	1301	20	68					
Rotary Vacuum Drum Filter	12-Sep	1508	Non-resp	1338	15	96	215	55%	506.48		
Rotary Vacuum Drum Filter	12-Sep	1509	Resp	1338	15	119					
Rotary Vacuum Drum Filter	12-Sep	1510	Non-resp	1338	15	77	165	53%	388.69		
Rotary Vacuum Drum Filter	12-Sep	1511	Resp	1338	15	88					
Rotary Vacuum Drum Filter	12-Sep	1512	Non-resp	1322	15	59	205	71%	482.92	1.0	
Rotary Vacuum Drum Filter	12-Sep	1513	Resp	1322	15	146					
Rotary Vacuum Drum Filter	12-Sep	1514	Non-resp	1322	15	68	238	71%	560.66		
Rotary Vacuum Drum Filter	12-Sep	1515	Resp	1322	15	170					
Rotary Vacuum Drum Filter	12-Sep	1516	Non-resp	1356	10	80	207	61%	731.45		
Rotary Vacuum Drum Filter	12-Sep	1517	Resp	1356	10	127					
Rotary Vacuum Drum Filter	12-Sep	1518	Non-resp	1356	10	58	177	67%	625.44		
Rotary Vacuum Drum Filter	12-Sep	1519	Resp	1356	10	119					
Rotary Vacuum Drum Filter	12-Sep	1520	Non-resp	1407	15	12	56	79%	131.92		
Rotary Vacuum Drum Filter	12-Sep	1521	Resp	1407	15	44					
Rotary Vacuum Drum Filter	12-Sep	1522	Non-resp	1407	15	20	63	68%	148.41		
Rotary Vacuum Drum Filter	12-Sep	1523	Resp	1407	15	43					
Rotary Vacuum Drum Filter	12-Sep	1524	Non-resp	1422	20	33	55	40%	97.17		
Rotary Vacuum Drum Filter	12-Sep	1525	Resp	1422	20	22					
Rotary Vacuum Drum Filter	12-Sep	1526	Non-resp	1422	20	25	45	44%	79.51		
Rotary Vacuum Drum Filter	12-Sep	1527	Resp	1422	20	20					
Rotary Vacuum Drum Filter	12-Sep	1532	Non-resp	1530	15	90	125	28%	294.46	10.0	

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Rotary Vacuum Drum Filter	12-Sep	1533	Resp	1530	15	35					
Rotary Vacuum Drum Filter	12-Sep	1534	Non-resp	1530	15	36	64	44%	150.77	3.0	
Rotary Vacuum Drum Filter	12-Sep	1535	Resp	1530	15	28					
Rotary Vacuum Drum Filter	12-Sep	1536	Non-resp	1546	15	47	68	31%	160.19	4.0	
Rotary Vacuum Drum Filter	12-Sep	1537	Resp	1546	15	21					
Rotary Vacuum Drum Filter	12-Sep	1538	Non-resp	1546	15	78	119	34%	280.33		
Rotary Vacuum Drum Filter	12-Sep	1539	Resp	1546	15	41				2.0	
Rotary Vacuum Drum Filter	12-Sep	1540	Non-resp	1601	15	82	195	58%	459.36	2.0	
Rotary Vacuum Drum Filter	12-Sep	1541	Resp	1601	15	113					
Rotary Vacuum Drum Filter	12-Sep	1542	Non-resp	1601	15	80	134	40%	315.67	3.0	
Rotary Vacuum Drum Filter	12-Sep	1543	Resp	1601	15	54					
Between Aging Tanks 1 and 2	12-Sep	7010	Non-resp	1333	15	102	259	61%	610.13		
Between Aging Tanks 1 and 2	12-Sep	7009	Resp	1333	15	157					
Between Aging Tanks 1 and 2	12-Sep	7012	Non-resp	1351	15	179	374	52%	881.04		
Between Aging Tanks 1 and 2	12-Sep	7011	Resp	1351	15	195					
Between Aging Tanks 1 and 2	12-Sep	7014	Non-resp	1510	15	41	117	65%	275.62		
Between Aging Tanks 1 and 2	12-Sep	7013	Resp	1510	15	76					
Between Aging Tanks 1 and 2	12-Sep	7016	Non-resp	1529	15	23	65	65%	153.12		
Between Aging Tanks 1 and 2	12-Sep	7015	Resp	1529	15	42					
Between Aging Tanks 1 and 2	12-Sep	7018	Non-resp	1548	24	57	184	69%	276.67		
Between Aging Tanks 1 and 2	12-Sep	7017	Resp	1548	24	127					
Between Aging Tanks 1 and 2	12-Sep	7020	Non-resp	1515	15	24	49	51%	115.43		
Between Aging Tanks 1 and 2	12-Sep	7019	Resp	1515	15	25					
Between Aging Tanks 1 and 2	12-Sep	7022	Non-resp	1535	15	18	43	58%	101.30		
Between Aging Tanks 1 and 2	12-Sep	7021	Resp	1535	15	25					
Between Aging Tanks 1 and 2	12-Sep	7026	Non-resp	1557	15	10	38	74%	89.52		
Between Aging Tanks 1 and 2	12-Sep	7025	Resp	1557	15	28					
Between Aging Tanks 1 and 2	12-Sep	7028	Non-resp	1615	15	0	250	100%	588.93		
Between Aging Tanks 1 and 2	12-Sep	7027	Resp	1615	15	250					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Control Room	13-Sep	7500	Non-resp	1045	15	51	97	47%	228.50		
Control Room	13-Sep	7501	Resp	1045	15	46					
Control Room	13-Sep	7502	Non-resp	1045	15	46	93	51%	219.08	0.0	
Control Room	13-Sep	7503	Resp	1045	15	47					
Control Room	13-Sep	7504	Non-resp	1101	20	55	100	45%	176.68		
Control Room	13-Sep	7505	Resp	1101	20	45					
Control Room	13-Sep	7506	Non-resp	1101	20	56	110	49%	194.35		
Control Room	13-Sep	7507	Resp	1101	20	54					
Control Room	13-Sep	7508	Non-resp	1122	15	72	123	41%	289.75		
Control Room	13-Sep	7509	Resp	1122	15	51					
Control Room	13-Sep	7510	Non-resp	1122	15	53	100	47%	235.57		
Control Room	13-Sep	7511	Resp	1122	15	47					
Control Room	13-Sep	7516	Non-resp	1137	20	76	115	34%	203.18	0.0	
Control Room	13-Sep	7517	Resp	1137	20	39					
Control Room	13-Sep	7518	Non-resp	1137	20	92	148	38%	261.48		
Control Room	13-Sep	7519	Resp	1137	20	56					
Incubation Room	13-Sep	8100	Non-resp	1303	20	36	222	84%	392.23		
Incubation Room	13-Sep	8101	Resp	1303	20	186					
Incubation Room	13-Sep	8104	Non-resp	1323	20	27	226	88%	399.29		
Incubation Room	13-Sep	8105	Resp	1323	20	199					
Incubation Room	13-Sep	8108	Non-resp	1343	20	37	246	85%	434.63		
Incubation Room	13-Sep	8109	Resp	1343	20	209					
Incubation Room	13-Sep	8112	Non-resp	1403	20	24	207	88%	365.72		
Incubation Room	13-Sep	8113	Resp	1403	20	183					
Incubation Room	13-Sep	8120	Non-resp	1424	20	28	224	88%	395.76		
Incubation Room	13-Sep	8121	Resp	1424	20	196					
Hall - outside incubation room	13-Sep	8102	Non-resp	1306	15	52	239	78%	563.02		
Hall - outside incubation room	13-Sep	8103	Resp	1306	15	187					
Hall - outside incubation room	13-Sep	8106	Non-resp	1321	20	84	284	70%	501.77		

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Hall - outside incubation room	13-Sep	8107	Resp	1321	20	200					
Hall - outside incubation room	13-Sep	8114	Non-resp	1342	20	62	263	76%	464.66		
Hall - outside incubation room	13-Sep	8115	Resp	1342	20	201					
Hall - outside incubation room	13-Sep	8118	Non-resp	1402	20	36	235	85%	415.19		
Hall - outside incubation room	13-Sep	8119	Resp	1402	20	199					
Hall - outside incubation room	13-Sep	8122	Non-resp	1428	20	64	267	76%	471.73		
Hall - outside incubation room	13-Sep	8123	Resp	1428	20	203					
Between Aging Tanks 1 and 2	13-Sep	7029	Resp	1022	15	102	178	43%	419.32		
Between Aging Tanks 1 and 2	13-Sep	7030	Non-resp	1022	15	76					
Between Aging Tanks 1 and 2	13-Sep	7031	Resp	1041	15	145	335	57%	789.16		
Between Aging Tanks 1 and 2	13-Sep	7032	Non-resp	1041	15	190					
Between Aging Tanks 1 and 2	13-Sep	7033	Resp	1059	15	148	329	55%	775.03		
Between Aging Tanks 1 and 2	13-Sep	7034	Non-resp	1059	15	181					
Between Aging Tanks 1 and 2	13-Sep	7035	Resp	1118	15	179	380	53%	895.17		
Between Aging Tanks 1 and 2	13-Sep	7036	Non-resp	1118	15	201					
Rotary Vacuum Drum Filter	13-Sep	1544	Non-resp	0825	15	150	247	39%	581.86	1.0	
Rotary Vacuum Drum Filter	13-Sep	1545	Resp	0825	15	97					
Rotary Vacuum Drum Filter	13-Sep	1546	Non-resp	0825	15	654	861	24%	2028.27		
Rotary Vacuum Drum Filter	13-Sep	1547	Resp	0825	15	207					
Rotary Vacuum Drum Filter	13-Sep	1548	Non-resp	0841	20	193	335	42%	591.87	1.0	
Rotary Vacuum Drum Filter	13-Sep	1549	Resp	0841	20	142					
Rotary Vacuum Drum Filter	13-Sep	1550	Non-resp	0841	20						
Rotary Vacuum Drum Filter	13-Sep	1551	Resp	0841	20	115					
Rotary Vacuum Drum Filter	13-Sep	1552	Non-resp	0904	15	47	115	59%	270.91	2.0	
Rotary Vacuum Drum Filter	13-Sep	1553	Resp	0904	15	68					
Rotary Vacuum Drum Filter	13-Sep	1554	Non-resp	0904	15	43	109	61%	256.77		
Rotary Vacuum Drum Filter	13-Sep	1555	Resp	0904	15	66					
Rotary Vacuum Drum Filter	13-Sep	1556	Non-resp	0919	15	7	26	73%	61.25	1.0	
Rotary Vacuum Drum Filter	13-Sep	1557	Resp	0919	15	19					

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Rotary Vacuum Drum Filter	13-Sep	1558	Non-resp	0919	15	11	34	68%	80.09		
Rotary Vacuum Drum Filter	13-Sep	1559	Resp	0919	15	23				1.0	
Rotary Vacuum Drum Filter	09-Sep	1012	Non-resp	1415	0						
Rotary Vacuum Drum Filter	09-Sep	1014	Non-resp	1415	0						
Rotary Vacuum Drum Filter	12-Sep	1528	Non-resp	1430	0						
Rotary Vacuum Drum Filter	12-Sep	1530	Non-resp	1430	0						
Background - paint shed	09-Sep	2012	Non-resp	1405	0						
Background - paint shed	09-Sep	2014	Non-resp	1405	0						
Control Room	10-Sep	3010	Non-resp	0845	0						
Background - paint shed north	11-Sep	c3036	Non-resp	0950	0						
Background - filter press in building	11-Sep	c3048	Non-resp	1145	0						
Background - filter press in building	11-Sep	c3052	Non-resp	1320	0						
Fermentor Agitator Shafts - F and E	10-Sep	4020	Non-resp	0905	0						
Fermentor Agitator Shafts - F and E	10-Sep	4022	Non-resp	0905	0						
Fermentor Agitator Shafts - F and E	10-Sep	4056	Non-resp	1334	0						
Fermentor Agitator Shafts - F and E	10-Sep	4058	Non-resp	1334	0						
Seed Fermentor	11-Sep	4508	Non-resp	1544	0						
Seed Fermentor	11-Sep	4510	Non-resp	1544	0						
Seed Fermentor	12-Sep	4532	Non-resp	0915	0						
Seed Fermentor	12-Sep	4534	Non-resp	0915	0						
Control Room	11-Sep	c6020	Non-resp	0932	0						
Control Room	11-Sep	c6022	Non-resp	0932	0						
Clean Room	10-Sep	7006	Non-resp	1642	0						
Between Aging Tanks 1 and 2	12-Sep	7024	Non-resp	1553	0						
Between Aging Tanks 1 and 2	13-Sep	7038	Non-resp	1135	0						
Control Room	13-Sep	7512	Non-resp	1130	0						
Control Room	13-Sep	7514	Non-resp	1130	0						
Clean Room	13-Sep	8110	Non-resp	1341	0						
Incubation Room	13-Sep	8116	Non-resp	1410	0						

(continued)

TABLE II. (continued)

Location	Date	Plate No.	Stage	Time	Minutes	CCFU	TCFU	PResp	CFU/m^3	Number	API
Rotary Vacuum Drum Filter	09-Sep	1013	Resp	1415	0						
Rotary Vacuum Drum Filter	09-Sep	1015	Resp	1415	0						
Rotary Vacuum Drum Filter	12-Sep	1529	Resp	1430	0						
Rotary Vacuum Drum Filter	12-Sep	1531	Resp	1430	0						
Background - paint shed	09-Sep	2013	Resp	1405	0						
Background - paint shed	09-Sep	2015	Resp	1405	0						
Control Room	10-Sep	3011	Resp	0845	0						
Background - paint shed north	11-Sep	c3037	Resp	0950	0						
Background - filter press in building	11-Sep	c3049	Resp	1145	0						
Background - filter press in building	11-Sep	c3053	Resp	1320	0						
Fermentor Agitator Shafts - F and E	10-Sep	4021	Resp	0905	0						
Fermentor Agitator Shafts - F and E	10-Sep	4023	Resp	0905	0						
Fermentor Agitator Shafts - F and E	10-Sep	4057	Resp	1334	0						
Fermentor Agitator Shafts - F and E	10-Sep	4059	Resp	1334	0						
Seed Fermentor	11-Sep	4509	Resp	1544	0						
Seed Fermentor	11-Sep	4511	Resp	1544	0						
Seed Fermentor	12-Sep	4533	Resp	0915	0						
Seed Fermentor	12-Sep	4535	Resp	0915	0						
Control Room	11-Sep	c6021	Resp	0932	0						
Control Room	11-Sep	c6023	Resp	0932	0						
Clean Room	10-Sep	7007	Resp	1642	0						
Between Aging Tanks 1 and 2	12-Sep	7023	Resp	1553	0						
Between Aging Tanks 1 and 2	13-Sep	7037	Resp	1135	0						
Control Room	13-Sep	7513	Resp	1130	0						
Control Room	13-Sep	7515	Resp	1130	0						
Clean Room	13-Sep	8111	Resp	1341	0						
Incubation Room	13-Sep	8117	Resp	1410	0						

TABLE III. Viable Sampling Summary

Sample Location	Mean (CFU/m^3)	St Dev (CFU/m^3)	Maximum (CFU/m^3)	Minimum (CFU/m^3)
Background - filter press in building	382.4	226.8	666.6	35.3
Background - paint shed	120.8	61.1	272.0	3.5
Background - paint shed north	478.2	152.6	638.4	216.7
Between Aging Tanks 1 and 2	531.6	188.1	895.1	89.5
Clean Room	3.2	4.4	12.3	0.0
Control Room	271.2	79.2	692.5	108.3
Fermentor Agitator Shafts - F and E	285.2	33.3	1015.3	38.8
Hall - outside incubation room	308.8	174.5	563.0	134.2
Incubation Room	220.8	176.7	434.6	31.8
Rotary Vacuum Drum Filter	345.1	153.8	2028.2	61.2
Sample Port - fermentor tank	705.7	266.6	983.5	335.6
Seed Fermentor	326.9	50.8	765.6	103.6

TABLE IV. Exploratory Viable Sampling Results

Location	Date	Plate No.	Minutes	CFU	TCFU	CFU/m^3
Background - paint shed	26-Aug	100	10	10	22	77.0
Background - paint shed	26-Aug	101	10	12		
Background - paint shed	26-Aug	102	10	275	298	1042.6
Background - paint shed	26-Aug	103	10	23		
Background - paint shed	26-Aug	104	15	28	93	216.9
Background - paint shed	26-Aug	105	15	65		
Background - paint shed	26-Aug	106	15	21	61	142.3
Background - paint shed	26-Aug	107	15	40		
Background - paint shed	26-Aug	110	5	3	10	70.0
Background - paint shed	26-Aug	109	5	7		
Background - paint shed	26-Aug	112	5	3	10	70.0
Background - paint shed	26-Aug	111	5	7		
Background - paint shed	26-Aug	108	0	1	2	
Background - paint shed	26-Aug	113	0	1		
Background - paint shed	26-Aug	115	0	0	1	
Background - paint shed	26-Aug	114	0	1		
Fermentor Agitator Shaft	26-Aug	116	10	10	26	91.0
Fermentor Agitator Shaft	26-Aug	117	10	16		
Fermentor Agitator Shaft	26-Aug	118	10	13	26	91.0
Fermentor Agitator Shaft	26-Aug	119	10	13		
Fermentor Agitator Shaft	26-Aug	120	10	13	31	108.5
Fermentor Agitator Shaft	26-Aug	121	10	18		
Fermentor Agitator Shaft	26-Aug	122	10	11	40	139.9
Fermentor Agitator Shaft	26-Aug	123	10	29		
Fermentor Agitator Shaft	26-Aug	124	5	4	14	98.0
Fermentor Agitator Shaft	26-Aug	125	5	10		
Fermentor Agitator Shaft	26-Aug	126	5	5	17	119.0
Fermentor Agitator Shaft	26-Aug	127	5	12		
Rotary Vacuum Drum Filter	26-Aug	128	5	35	107	748.7
Rotary Vacuum Drum Filter	26-Aug	129	5	72		
Rotary Vacuum Drum Filter	26-Aug	130	5	87	125	874.6
Rotary Vacuum Drum Filter	26-Aug	131	5	38		
Rotary Vacuum Drum Filter	26-Aug	140	5	5	13	91.0
Rotary Vacuum Drum Filter	26-Aug	141	5	8		
Rotary Vacuum Drum Filter	26-Aug	134	5	63	84	587.8
Rotary Vacuum Drum Filter	26-Aug	135	5	21		
Rotary Vacuum Drum Filter	26-Aug	132	7.5	31	53	247.2
Rotary Vacuum Drum Filter	26-Aug	133	7.5	22		
Rotary Vacuum Drum Filter	26-Aug	136	7.5	21	27	125.9
Rotary Vacuum Drum Filter	26-Aug	137	7.5	6		
Rotary Vacuum Drum Filter	26-Aug	138	0	0	1	
Rotary Vacuum Drum Filter	26-Aug	139	0	1		

(continued)

TABLE IV. (continued)

Location	Date	Plate No.	Minutes	CFU	TCFU	CFU/m^3
Rotary Vacuum Drum Filter	26-Aug	142	0	3	4	
Rotary Vacuum Drum Filter	26-Aug	143	0	1		
Control Room	27-Aug	144	20	93	146	255.4
Control Room	27-Aug	145	20	53		
Control Room	27-Aug	146	20	103	150	262.4
Control Room	27-Aug	147	20	47		
Control Room	27-Aug	148	20	107	145	253.6
Control Room	27-Aug	149	20	38		
Control Room	27-Aug	150	20	93	135	236.2
Control Room	27-Aug	151	20	42		
Control Room	27-Aug	152	20	41	80	139.9
Control Room	27-Aug	153	20	39		
Control Room	27-Aug	154	20	65	109	190.7
Control Room	27-Aug	155	20	44		
Seed Tank	27-Aug	155'	15	26	39	91.0
Seed Tank	27-Aug	156	15	13		
Seed Tank	27-Aug	157	15	2	2	4.7
Seed Tank	27-Aug	158	15	0		
Seed Tank	27-Aug	159	15	48	72	167.9
Seed Tank	27-Aug	160	15	24		
Seed Tank	27-Aug	161	15	39	68	158.6
Seed Tank	27-Aug	162	15	29		
Seed Tank	27-Aug	163	10	14	21	73.5
Seed Tank	27-Aug	164	10	7		
Seed Tank	27-Aug	165	10	13	22	77.0
Seed Tank	27-Aug	166	10	9		
Seed Tank	27-Aug	167	0	1	1	
Seed Tank	27-Aug	168	0	0		
Seed Tank	27-Aug	169	0	1	1	
Seed Tank	27-Aug	170	0	0		
Transfer Room	27-Aug	172	20	14	36	63.0
Transfer Room	27-Aug	171	20	22		
Transfer Room	27-Aug	174	20	16	30	52.5
Transfer Room	27-Aug	173	20	14		
Transfer Room	27-Aug	176	15	21	35	81.6
Transfer Room	27-Aug	175	15	14		
Transfer Room	27-Aug	178	15	8	18	42.0
Transfer Room	27-Aug	177	15	10		
Hall - outside transfer room	27-Aug	179	20	58	97	169.7
Hall - outside transfer room	27-Aug	180	20	39		
Hall - outside transfer room	27-Aug	181	20	73	123	215.2
Hall - outside transfer room	27-Aug	182	20	50		

(continued)

TABLE IV. (continued)

Location	Date	Plate No.	Minutes	CFU	TCFU	CFU/m^3
Hall - outside transfer room	27-Aug	183	20	36	48	84.0
Hall - outside transfer room	27-Aug	184	20	12		
Hall - outside transfer room	27-Aug	185	20	39	53	92.7
Hall - outside transfer room	27-Aug	186	20	14		
Hall - outside transfer room	27-Aug	187	0	1	1	
Hall - outside transfer room	27-Aug	188	0	0		
Hall - outside transfer room	27-Aug	189	0	1	1	
Hall - outside transfer room	27-Aug	190	0	0		

TABLE V. Total Dusts Sampling Results

Location	Date	Filter	Flow Rate (cfm)	Time (hr)	Dust ug	CDust ug	mg/m^3
Weigh Station	10-Sep	1	52	7.43	113.58	113.66	0.17
Weigh Station	10-Sep	7	0		-0.40		
Weigh Station	11-Sep	8	52	8.29	87.05	87.13	0.12
Weigh Station	11-Sep	9	0		-0.12		
Weigh Station #	12-Sep	15	52		6.88	6.96	
Weigh Station	12-Sep	16	0		0.12		
Weigh Station	13-Sep	22	52	4.19	135.13	135.21	0.37
Dump Station #	10-Sep	5	50	4.44	41.41	41.49	0.11
Dump Station	11-Sep	11	50	7.70	75.14	75.22	0.11
Dump Station #	12-Sep	17	50		9.93	10.01	
Filter Press	10-Sep	2	46	7.10	56.35	56.43	0.10
Filter Press	11-Sep	10	46	7.77	73.04	73.12	0.12
Filter Press	12-Sep	20	46	5.80	66.13	66.21	0.15
Filter Press	13-Sep	23	46	4.31	39.72	39.80	0.12
Aging Tanks	10-Sep	3	48	6.93	55.65	55.73	0.10
Aging Tanks	11-Sep	14	42	6.67	63.44	63.52	0.13
Aging Tanks	12-Sep	21	42	5.69	20.75	20.83	0.05
Fermentor Tank - agitator shaft	10-Sep	4	42	6.19	37.40	37.48	0.08
Fermentor Tank - agitator shaft	10-Sep	6	0		0.01		
Fermentor Tank - agitator shaft	11-Sep	12	42	6.90	41.72	41.80	0.08
Fermentor Tank - agitator shaft	11-Sep	13	0		-0.25		
Fermentor Tank - agitator shaft	12-Sep	18	42	5.76	16.70	16.78	0.04
Fermentor Tank - agitator shaft	12-Sep	19	0		0.16		