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LADISH MALTING CO.
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I. SUMMARY

In October of 1993, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation (HHE) at the Ladish Malting Company of Jefferson, Wisconsin. The request cited occupational health concerns from worker exposures to mycotoxins during barley storage and malting operations. Mycotoxin exposures from *Fusarium* fungi were cited in the request. The presence of these fungi and mycotoxins in the 1993 barley crop was attributed by company officials to the rainy growing season experienced in some barley growing regions. On November 3 to 5, 1993, NIOSH investigators conducted a medical and industrial hygiene survey at the Ladish Malting plant.

Viable fungi were cultured in all barley, malt, and dust samples; fungi of the *Fusarium* genus were the most abundant in most of the 1993 barley and dust samples. The trichothecene mycotoxins deoxynivalenol (DON) and 15 acetyl-DON were detected in 1993 barley samples. Trichothecene mycotoxins were not detected in a sample of 1992 barley. DON mycotoxin was also detected in samples of settled dust indicating the potential for aerosolization of mycotoxins and worker exposure. The plant operations sampled during the survey were worse case exposure scenario involving the cleaning of both the elevators and the plant by blowing and sweeping dusts. Some of the personal breathing zone (PBZ) and area concentrations of airborne grain dust were high by comparison to existing exposure standards and criteria of the Occupational Safety and Health Administration (OSHA), NIOSH, and the American Conference of Governmental Industrial Hygienists (ACGIH); all of the PBZ and area concentrations of endotoxin in air were high by comparison to estimated human thresholds for respiratory response. All workers sampled used respiratory protection to reduce these exposures. However, the type of respirator used by workers (the disposable particulate respirator) would not have an adequate protection factor for some of the higher dust and endotoxin concentrations.

Twenty-one workers participated in the medical portion of the survey. These individuals were invited to participate because they worked in the barley and malt areas and were felt to have the greatest possibility for exposure to the toxins. All the participants answered a questionnaire about jobs, symptoms, medical condition, smoking history, and the use of personal protective equipment. They also had their temperature taken and recorded before and after the work shift and again the following day upon return to work.

All the participants except one worked the day shift. Relative to their pre-shift temperature, none of the participants had a significant temperature increase either immediately after their work shift or 24 hours after the beginning of their work shift. All reported that they wore respiratory protection at least part of the time; 43% reported using it less than 50% of the time. Six reported having morning cough with phlegm for more than 3 months a year for more than 2 years, and five of these felt that their cough could be work-related. However, of symptoms which appeared after the start of the work shift, the most commonly reported were eye irritation (8), tiredness (7), and throat irritation (5). Thirteen (62%) reported at least one symptom within 24 hours of the start of their work shift.

Trichothecene mycotoxins (deoxynivalenol and 15 acetyl-DON) were detected in bulk samples of barley and in samples of settled dust, indicating potential for aerosolization of mycotoxins and worker exposure. Air samples indicated potential for high exposures to grain dusts and endotoxins. Worker health effects reported on the day of the survey were of an irritant nature. However, the potential exists for the development of a hypersensitivity or toxic syndrome unless worker exposures are controlled as recommended in section IX of this report.

KEY WORDS: SIC 2083 (malting operations), Mycotoxins, Fungi, Barley, ODTs, Malting

II. INTRODUCTION

On October 26, 1993, the National Institute for Occupational Safety and Health (NIOSH) received a confidential request for a health hazard evaluation (HHE) at the Ladish Malting Company of Jefferson, Wisconsin. The request cited occupational health concerns related to the potential for worker exposures to mycotoxins from barley and malt products; mycotoxin exposures from the *Fusarium* fungal species were cited in the request. On November 3 to 5, 1993, NIOSH investigators conducted a medical and industrial hygiene survey. In March of 1995, an interim report of environmental sampling results was distributed.

III. PROCESS DESCRIPTION

The Ladish Malting Company's Jefferson, Wisconsin, plant is one of the largest barley malting operations in the country. The company has been in operation since the 1890's and currently employs approximately 90 workers, including six lab personnel, at this facility.

Malting is a process where barley grain is received, cleaned, germinated, heat dried, aged, and blended to produce malt. The malt from this operation is used primarily in the beer brewing industry. Barley arrives at the plant predominantly by rail car. The grain is unloaded and placed into large grain elevators. Next, the barley is cleaned, graded according to size, and transported by conveyor belts to the malting operations in the malt house. During malting, the barley is immersed in water containers called steeping tanks. After a controlled period of time, the grain is discharged from the water tanks into a series of growing or germinating compartments, where sprouting occurs. It is during this process that barley starch is changed to maltose, which is the fermentable sugar used in the brewing process. Germination is terminated at a specific point to produce the desired malt qualities; germinated barley is referred to as green malt at this point. To terminate germination, the green malt is conveyed to one of the kilns where hot dry air is used to halt the germination process and also to reduce the moisture content of the malt. After drying, the barley malt is dropped into malt hoppers and conveyed to malt elevators for aging and curing. In a final step, the malt is blended, loaded, and shipped to market.⁽¹⁾

Barley, like other grains, is subject to fungal contamination. Fungi are ubiquitous in nature and have the ability to catabolize numerous organic substrates. Fungal contamination of grains is influenced by handling and storage conditions such as temperature, humidity, and moisture content. Fungi of the *Fusarium* genus are common and can be found in grain and a variety of organic feed materials under both field and storage conditions.^(2,3) Officials at Ladish Malting Company

reported that some of the 1993 barley crop contained visible mold growth; this reddish brown surface growth was believed to be fungi of the *Fusarium* genus. Ladish Malting company was screening all incoming barley shipments for the presence of a fungal mycotoxin (deoxynivalenol) produced by fungi of the *Fusarium* genus. Deoxynivalenol was detected in some of the barley shipments received this year (1993) using an enzyme-linked immunosorbent assay (ELISA). The mold growth and subsequent mycotoxin generation in the barley crop was attributed to the wet conditions experienced in the Midwest grain growing regions during the summer and fall of 1993.

IV. METHODS

To address the occupational health concerns raised by this HHE request, an environmental and medical survey was conducted; this survey was completed over a 3-day period. Environmental evaluations included: 1) sampling settled dusts and bulk materials for viable fungi and mycotoxins; and 2) air sampling for total and respirable dusts, particle size distributions, endotoxins, and viable fungi. Company records on mycotoxin sampling and analysis were reviewed, and the existing dust exposure controls were observed. Medical evaluations included: 1) administration of a medical and work practice questionnaire; 2) pre- and post-shift measurement of body temperature; and 3) review of company medical records.

A. ENVIRONMENTAL METHODS

Air samples were collected to measure concentrations of total dust, respirable dust, endotoxins, and particle size distributions. Both personal and area air samples were collected. Personal samples were collected to measure exposures to total dust and total endotoxin. Area samples were collected for all of the analytes mentioned above. Area samples were also collected for qualitative analysis of fungal organisms in air. Table 1 provides details on the methods used to collect these samples.⁽⁴⁻¹²⁾ The plant operations sampled during the survey were worse-case involving the cleaning of both the elevator and the plant by blowing and sweeping dust.

Bulk samples of settled dust, barley grain, and malt were collected in sterile, pyrogen-free containers from various locations in the plant. These samples were analyzed qualitatively for viable fungi. Fungal cultures were grown in liquid broth (yeast-malt) in shake culture and plated on rose bengal agar with streptomycin (RBS). The samples were incubated at 25 degrees Centigrade (°C). After incubation, the predominant fungal genera growing in each sample were identified. These samples were also submitted for analysis for trichothecene mycotoxins including deoxynivalenol; the samples were

analyzed under contract with Romer Labs¹ using thin layer chromatography (TLC). The samples of settled dust and bulk materials were also analyzed for endotoxins by the Lymulus ameobocyte lysate test (LAL).⁽⁴⁾

B. MEDICAL METHODS

All employees working the day shift in the areas of potential exposure (barley and malt elevators) were invited to participate in the medical portion of the study. A questionnaire was developed to gather information about present work activities, previous work, symptoms associated with work, and smoking history. The questionnaire was administered by a NIOSH interviewer at the beginning of the work shift. A one-page questionnaire was also completed after the work shift, and a one-page symptom questionnaire was sent home with the worker to be completed the following morning. These questionnaires were intended to determine if symptoms had developed during the day or after the worker had gone home for the day.

The temperature measurements were made using a thermoscan instant thermometer. A probe with a disposable cover was placed into the ear canal for approximately 3 seconds, and the temperature reading was observed and recorded. Temperatures were measured at the beginning and end of the work shift and again at the beginning of work the following day. This was done to determine if anyone had developed febrile illness consistent with organic dust toxic syndrome (ODTS) during the day after working with the grain.⁽¹³⁾

V. EVALUATION CRITERIA

A. ENVIRONMENTAL EVALUATION CRITERIA

As a guide to the evaluation of the hazard posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. These evaluation criteria are guidelines, not absolute limits between safe and dangerous levels of exposure. A small percentage of workers may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

¹ Romer Labs Inc., 1301 Stylemaster Drive, Union, MO 63084.

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations,^(14,15) 2) the American Conference of Governmental Industrial Hygienist' (ACGIH) Threshold Limit Values (TLVs),⁽¹⁶⁾ and 3) the U.S. Department of Labor (OSHA) Occupational Health Standards.⁽¹⁷⁾ Both NIOSH recommendations and current ACGIH TLVs usually are lower than OSHA permissible exposure limits (PELs) because the OSHA standards may be required to take into account the feasibility of controlling exposures in various industries where the agents are used. The NIOSH recommended exposure limits (RELs), by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits (STEL) or ceiling © values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures. Substances that can contribute significant exposure by passage through the skin or mucus membranes are assigned a specific (SKIN) notation.

The occupational exposure criteria and standards for air contaminants measured during this HHE survey are as follows⁽¹⁴⁻¹⁷⁾:

SUBSTANCE	NIOSH REL	ACGIH TLV	OSHA PEL
Grain Dust in Air (total)	4 mg/m ³ - TWA	4 mg/m ³ - TWA	10 mg/m ³ -TWA
Trichothecene Mycotoxins in Air	No REL	No TLV	No PEL
Bacterial Endotoxins in Air	No REL	No TLV	No PEL

B. TOXICOLOGY INFORMATION

OCCUPATIONAL RESPIRATORY PROBLEMS

Overexposure to grain dust has been recognized as a cause of occupational respiratory problems for many years. Common to agricultural dusts, including grain dusts, is the great variability in both dust composition and dust exposure levels. Several different types of respiratory health effects are common to agricultural dust exposures. Potential health problems associated with grain dust exposures can include inflammatory diseases of the eyes, nose, and skin either by direct irritation or by immunological mechanisms. Grain dust exposures have also been associated with respiratory diseases including grain fever, hypersensitivity pneumonitis, occupational asthma and rhinitis, and bronchitis.

OCCUPATIONAL ASTHMA

Occupational asthma is a reversible obstruction of the airways causally related to the inhalation of agents from the work environment.⁽¹⁸⁾ Asthma is characterized by an increased responsiveness of the airways to various stimuli and manifested by slowing of forced expiration. Asthma is commonly a disease of immunological origin often affecting atopic individuals.⁽¹⁸⁻²²⁾ (Atopy describes a group of common allergic diseases in which there is an inherited tendency to produce IgE antibodies to allergens on inhaled organic particles.) IgE mediated allergic reactions have been strongly implicated in the pathogenesis of many forms of occupational asthma in conjunction with abnormal autonomic regulation of airway smooth muscle (airway hyper-responsiveness). The interaction of antigen and antibody trigger a series of reactions that result in the release of pharmacological mediators such as histamine, serotonin, eosinophil and neutrophil chemotactic factors, prostaglandins, bradykinins, and others resulting in an asthmatic reaction.⁽¹⁹⁻²¹⁾ Two of the primary features of this asthmatic response are bronchial muscle contraction and increased mucus secretion.⁽¹⁹⁻²¹⁾ In the etiology of

occupational asthma, sensitization to a particular antigen is followed by increased airway responsiveness to that antigen. After sensitization develops, symptoms may result from exposures to even small amounts of that antigen. The clinical manifestations of an asthmatic response are characterized by dyspnea, wheezing, chest tightness, and cough. Asthmatic response can be triggered by a growing list of both natural and synthetic substances including grain products, microorganisms such as fungi, and feed storage mites.⁽¹⁸⁻²¹⁾

Rhinitis is defined as inflammation of the mucous membranes of the nasal cavity and sinuses. Allergic rhinitis, often called hay fever, is characterized clinically by edema of the nasal mucosa with accompanying sneezing, nasal discharge and nasal obstruction. Occupational rhinitis can be caused by many of the agents in organic dusts that cause asthmatic response. Both occupational rhinitis and asthma can exist concurrently.⁽¹⁸⁻²⁰⁾

Chronic Bronchitis

Chronic bronchitis is one of the most prevalent respiratory health problems among agricultural workers commonly described among individuals handling grains.^(18,23) Chronic bronchitis is defined as chronic sputum production and is associated with chronic cough. It is characterized by hyperplasia and hypertrophy of the mucus secreting cells of the bronchial mucous glands with hyperplasia of the surfaces of large to medium airways and with goblet cell metaplasia in the small airways.^(18,21) Resulting morphologic changes include bronchial enlargement and edema of the bronchi. These pathological sequelae result in predominant clinical symptoms including increased mucus secretions, and cough. The presence of dyspnea and hemoptysis (coughing up blood) accompanies more serious, progressive disease. Lung function typically shows an obstructive pattern with a reduction in FEV₁ (and often FVC) both over a working shift and with time.^(18,20) Exposures to high concentrations of organic dusts, especially those containing grain or cotton materials, have been identified as a risk factor for chronic bronchitis. Cigarette smoking is also identified as a significant factor in the development of bronchitic symptoms.^(20, 24)

Hypersensitivity Pneumonitis

Hypersensitivity pneumonitis is an immunologically mediated pulmonary disease resulting from sensitization and recurrent exposure to a variety of organic components in agricultural dusts. Hypersensitivity pneumonitis is commonly referred to as extrinsic allergic alveolitis, allergic alveolitis, or by other terms specific to the environment causing disease e.g., farmers lung, mushroom workers lung, etc.^(18,19,20) A characteristic immunologic feature is the demonstration of serum precipitating antibodies against environmental

antigens. Hypersensitivity pneumonitis is characterized by diffuse mononuclear inflammation of the terminal bronchioles and alveoli. A characteristic disease feature is the presence of large granulomas during acute episodes. Alveolar lavage studies during acute episodes show a predominance of lymphocytes. Repeated insults and persistent chronic inflammation can result in the development of diffuse interstitial fibrosis. Chest radiographs commonly show an interstitial pattern of fibrosis and spirometry is commonly consistent with a restricted disease pattern. Pathogenesis is believed to involve either humoral immunity (immune-complex disease), cellular immunity, or both mechanisms; however, there is uncertainty regarding the exact immune mechanism(s) responsible for clinical disease. The clinical presentation of hypersensitivity pneumonitis depends on the degree and duration of exposure, the immunologic response of the host, and the antigenicity of the dust. Clinically, hypersensitivity pneumonitis can present in both acute and chronic forms. The acute episode is characterized by fever, muscular aches, dry cough, dyspnea, and general malaise occurring approximately 4 to 8 hours after exposure. Symptoms generally reach a peak approximately 8 hours after exposure and subside within 12 to 24 hours. In the chronic form, symptoms are predominately respiratory in nature and include progressive dyspnea and cough. Anorexia and weakness are also possible symptoms. This form of disease is generally seen in individuals chronically exposed to small amounts of antigen. An inherent danger in chronic disease is the progression to irreversible pulmonary fibrosis. A number of etiologic agents have been associated with hypersensitivity pneumonitis. Many agents in organic dusts are capable of causing hypersensitivity pneumonitis. Thermophilic actinomycete bacteria are recognized as an etiologic agent in many cases of hypersensitivity among farm workers (Farmers Lung) handling hay. Other potential antigens capable of causing disease include fungi and their spores, amoeba, bacteria, avian proteins, organic insecticides, and others.^(18,19,20,23,25)

Organic Dust Toxic Syndrome

Organic dust toxic syndrome (ODTS) is a nonallergic, self-limited illness producing acute febrile symptoms following respiratory exposures to high concentrations of organic dusts. Several varieties of toxic syndromes have been described and may comprise descriptions of the same disease, ODTS, in different work environments; among these are pulmonary mycotoxicosis, silo unloaders syndrome, grain fever, and toxin fever. ODTS is characterized by an elevated white blood cell count, and polymorphonuclear leukocytes are typically seen on bronchoalveolar lavage. Lung biopsies have demonstrated acute inflammatory reactions in the lung during episodic disease. Chest radiographs and spirometry are usually normal. Clinical symptoms include fever, muscle and joint pains, headache, and other symptoms resembling influenza. Symptoms generally develop 4 to 6 hours following massive dust

exposures. A characteristic aspect of ODTS is the occurrence of disease in clusters with a higher rate of attack among exposed individuals. These symptoms are self-limiting and recovery is common in approximately 24 - 72 hours, although, recurrent episodes can occur and are common on reexposure. Progression to chronic respiratory disease has not been demonstrated. ODTS typically follows massive exposures to organic dusts. Exposures to hays, oats, and wood chips contaminated with large numbers of microorganisms have been associated with the development of disease. Bacterial endotoxin in organic dusts as well as other microbiological agents, are suspected etiologic agents.^(18,23,24,25)

In the assessment of respiratory health problems from agricultural dusts, it is important to consider the multifactorial nature of disease etiology. The nature of the disease outcome is often dependent on both host and environmental factors. This makes the clinical aspects of disease identification and study complex. Overlapping mixed respiratory symptoms complicates disease diagnosis and makes exposure assessment and control more difficult. These factors complicate the evaluation of occupational health problems.^(18,24)

TOXICOLOGY OF SPECIFIC GRAIN DUST CONSTITUENTS

Fungi

Fungi are a common constituent of agricultural dusts such as grain dusts and are a recognized exposure hazard. While fungi are ubiquitous, overexposure to fungi can cause human health problems in several ways; these include direct fungal infections (mycoses), allergic reactions (e.g., asthma), hypersensitivity reactions (e.g., hypersensitivity pneumonitis), and by the production of toxic metabolites called mycotoxins.⁽²⁾ Respiratory exposures to fungi and organic dusts containing fungal constituents can cause many of the occupational respiratory diseases described above. Those respiratory diseases commonly associated with fungal exposures would include asthma and rhinitis, hypersensitivity pneumonitis, and organic dust toxic syndrome (ODTS).

Fungi of the *Fusarium* genera have been described to infect the eyes causing acute keratitis, corneal ulcers, and acute conjunctivitis.⁽³⁾

Currently, there are no ACGIH, NIOSH, or OSHA occupational exposure standards or recommendations for fungi.

Mycotoxins

Mycotoxins are toxic substances produced by fungi during secondary growth conditions. Mycotoxins can be produced by several different fungi and the

chemical nature of the mycotoxin is generally species specific. Some of the more common mycotoxins recognized to cause human health problems include aflatoxin, sterigmatocysin, ochratoxin, patulin, zearalenone, and the trichothecene mycotoxins. Mycotoxins can be produced by fungi that are ubiquitous to many occupational environments such as *Penicillium*, *Aspergillus*, *Fusarium*, and other genera. Fungal colonization of several agricultural commodities has been linked to mycotoxin contamination; these include corn, peanuts, milk, grains, apple products, rice, and others.^(2,26,27)

Most of the data on the health effects of mycotoxin exposures are derived from studies on the consumption of mycotoxins in foods. Ingestion of mycotoxins can result in a variety of health problems including damage to the liver, nervous system, kidneys, and skin. Some mycotoxins are recognized carcinogens, mutagens, and teratogens.^(2,26,27) The nature of the health problems from mycotoxin consumption is dependent on several factors such as the type of mycotoxin ingested, the amount ingested, as well as a number of host factors. The trichothecene mycotoxins, produced by fungi of the *Fusarium* genera, comprise approximately 40 different chemicals called sesquiterpenoids containing the trichothecene nucleus. Human consumption of trichothecene mycotoxins in millet, wheat, and barley produced symptoms including vomiting, skin inflammation, diarrhea, multiple hemorrhage, and others; the consumption of trichothecene mycotoxins in these grain products is sometimes lethal. The acute LD 50's for many of the trichothecenes are 0.5 to 1.0 mg/kg and they are quite toxic to mammals. The Japanese "red mold disease," attributed to trichothecene mycotoxin consumption, is characterized by vomiting and diarrhea in humans, and congestion and hemorrhage in multiple organs of animals. Many of the trichothecene mycotoxins produce similar health effects following consumption; these can include vomiting, diarrhea, hemorrhage, nervous system involvement, blood and bone marrow destruction. In general, trichothecene mycotoxins are also subjects of concern as possible carcinogens, mutagens, and genotoxic agents. Deoxynivalenol (DON) and 15 acetyl-deoxynivalenol (15 acetyl-DON) are trichothecene mycotoxins. Ingestion of DON, commonly referred to as vomitoxin, or 15 acetyl-DON could produce the symptoms described above as characteristic of trichothecene mycotoxins.^(26,28-30)

The health effects from respiratory exposures to mycotoxins is an area that is less widely studied than the health effects from mycotoxin ingestion. Since mycotoxins are largely nonvolatile, most respiratory exposure to mycotoxins would occur by inhalation of aerosolized spores, hyphae, and small particles of fungal substrate.⁽²⁾ Massive exposures to fungal contaminated agricultural materials can cause an acute, febrile pattern of respiratory illness referred to as ODTS. The term *pulmonary mycosis* has also been used to describe this type of acute febrile respiratory illness; although, there is still uncertainty regarding the etiologic agents responsible for this type of illness. Both fungi

and fungal mycotoxins are considered a possible cause along with other agents such as gram-negative bacteria and bacterial endotoxins.^(2,26-30) At present, there are no OSHA standards for occupational respiratory exposures to mycotoxins. Neither NIOSH or ACGIH have occupational exposure recommendations for mycotoxins.⁽¹⁴⁻¹⁷⁾

Endotoxins

Endotoxins are lipopolysaccharide substances contained in the cell wall of Gram-negative bacteria. The inhalation of endotoxins can induce a variety of biological responses including inflammatory, immunological, and hemodynamic activity. The pulmonary macrophage is extremely sensitive to the effects of endotoxins and a primary target cell for endotoxin induced pulmonary injury following respiratory exposure. Exposures to endotoxins have been reported to cause acute fever, dyspnea, chest tightness, coughing, and decreases in pulmonary function. Illnesses possibly associated with endotoxin exposure include byssinosis, HP, asthma, and ODS.⁽³¹⁻³⁴⁾ There are no OSHA, ACGIH, or NIOSH standards or criteria for occupational exposures to endotoxin. The scientific literature contains research describing human threshold exposure limits for endotoxins. The lowest endotoxin exposure reported to cause adverse pulmonary response was measured in exposure studies among subjects sensitive to cotton dusts, 9 nanograms of elutriated endotoxin per cubic meter of air (ng/m^3); this concentration is equivalent to approximately 90 endotoxin units per cubic meter of air (EU/m^3). Threshold endotoxin exposures among healthy human subjects exposed to cotton dusts are reported by Rylander as approximately 1000 to 2000 EU/m^3 for an across shift acute pulmonary response (decline in FEV_1) and 5000 to 10,000 EU/m^3 for fever.⁽³¹⁻³⁴⁾

VI. RESULTS

A. ENVIRONMENTAL

Table 2 provides information on the fungal organisms found in bulk samples of barley grain, barley malt, settled dust, and total airborne dust. The organisms are listed in the order of their relative abundance in the samples. Aside from yeasts, fungal organisms of the *Fusarium* genus were among the most common organisms identified in bulk barley, settled dust, and airborne dusts from the barley elevators. Other fungal organisms were also detected in these samples as indicated in the table.

Table 3 provides information on Trichothecene mycotoxins in samples of barley, barley malt, and settled dust. Deoxynivalenol and 15 acetyl-DON were the trichothecene mycotoxins identified in these samples. These mycotoxins were detected only in the bulk barley and settled dust samples. Mycotoxins were not detected in the bulk barley sample from elevator G10, the control sample of barley from the crop of the previous year (1992). Trichothecene mycotoxin concentrations are presented in parts per million parts by weight (PPM); detection limits for each trichothecene mycotoxin are also presented in PPM.

Table 4 presents information on endotoxin concentrations in barley, barley malt, and settled dust samples. Concentrations are presented in endotoxin units per milligram of dust (EU/mg).

Table 5 presents personal and area sampling results for total dust and total endotoxin samples. Dust concentrations and exposures are presented in milligrams of dust per cubic meter of air (mg/m^3); endotoxin concentrations and exposures are presented in endotoxin units per cubic meter of air (EU/m^3). The two area respirable dust samples were voided due to sampling pump failure during the sampling period; no respirable dust concentrations are reported. Table 6 provides summary statistics on the dust and endotoxin concentrations. Included in this table are the number of samples, the arithmetic mean, the standard deviation (STD), and the range from low to high.

B. MEDICAL

Of the approximately 90 Ladish employees, 21 were scheduled to work the barley and malt areas (20 on the day shift and one on the midnight shift) on the date that NIOSH personnel visited the plant. Of the 21 who participated in this survey, 12 worked in the malt area, 7 in barley, and 2 in both. All said that they wear respiratory protection at work, though only 9 (43%) wear it at least 80% of the time.

The median age of the participants was 41, and the smoking history was divided almost equally among current (6), former (7), and never smokers (8). The tenure of these employees at Ladish ranged from 3 to 25 years, and almost half of the participants (9) reported that they had also worked in other dusty occupations.

None of the participants were observed to have a fever when their temperatures were measured immediately after their work shift was completed or 24 hours after the beginning of their work shift.

Six (29%) of the participants reported a cough for more than 3 months a year and for more than 2 years. Two reported chest tightness temporally related to work, one of these also reported having cough. Only one said that he had flu-like symptoms in the past 12 months, but he could not relate it to any specific activity and also reported never having had chest tightness in connection with work. Three participants reported having hay fever, and one reported having asthma. The one worker with asthma answered yes to having wheezing, chest tightness, and breathlessness. He was a former smoker.

In the first questionnaire, participants were asked about several chest symptoms and general symptoms, whether they had the symptoms often (more than a third of the time), and whether the symptoms were related to work (Table 7). The most prevalent symptoms were eye irritation and cough with phlegm. They were asked again about the symptoms at the end of the work shift and the next morning. The second most prevalent complaint at the end of the work shift was of tiredness; this had not been reported by anyone previously (Table 8).

Five participants thought symptoms were worse on a particular day. However, the symptoms and days were all different and not consistent with any illness pattern. Two participants reported other symptoms that they thought were related to work, but neither was respiratory.

VII. DISCUSSION

The occupational health concerns cited in this HHE request involved potential for worker exposures to mycotoxins present in the 1993 barley crop received from some barley growing regions. The presence of mycotoxins in the 1993 barley crop was attributed by company officials to the previous rainy growing season experienced in some barley growing regions. Fungi of the *Fusarium sp.* were listed on the HHE request as a potential source of contamination in the barley crop and a source of the mycotoxins. Company sampling and analysis indicated the presence of the mycotoxin deoxynivalenol in some of the 1993 barley samples.

Bulk samples of barley, malt, settled dust, and airborne dust were collected to assess viable fungal organisms; fungi were cultured from all of these samples. Yeasts were the most abundant fungal organism cultured in every sample collected. Fungi of the *Fusarium* genera were common and one of the most abundant molds cultured from the bulk barley, settled dust, and airborne dust samples. *Fusarium* genera were not found in the bulk malt samples or in the grain sample collected from Elevator G-10. The bulk barley sample from this elevator (G-10) was collected as a control from an elevator that contained older barley from the previous year's crop (the 1992 barley crop); this crop was not identified by company officials as one contaminated with *Fusarium* fungi and mycotoxins. Other fungi present in the barley samples included *Cladosporium sp.*, *Penicillium sp.*, *Bipolaris sp.*, *Alternaria sp.*, and others. *Alternaria*, *Cladosporium*, and *Aspergillus glaucus* were the fungal organisms cultured from the malt samples. Based on the fungal organism identified in these samples and their relative abundance, additional samples were submitted for trichothecene mycotoxin analysis.

Trichothecene mycotoxins, produced by fungi of the *Fusarium* genera, were identified in bulk samples of 1993 barley and in samples of settled dust from the barley elevators G and A. These mycotoxins were not detected in the 1992 barley or in the barley malt sample. The trichothecene mycotoxins identified in the barley samples included DON and 15 acetyl-DON. Deoxynivalenol (commonly called vomitoxin or DON) was present at quantifiable levels in all 3 barley samples collected from 1993 crop elevators; concentrations ranged from 2.6 to 6.5 ppm by weight. The DON concentrations in the two settled dust samples were 0.8 ppm (elevator G) and 2.5 ppm (Elevator A). The trichothecene mycotoxin 15 acetyl-DON was also quantified in all three bulk samples of 1993 barley at concentrations ranging from 0.2 ppm to 0.6 ppm. The presence of trichothecene mycotoxins in barley and settled (airborne) dust samples indicates

that there is the potential for worker exposure to deoxynivalenol and 15 acetyl-DON through the processing of contaminated barley. At present, there are no occupational exposure standards for trichothecene mycotoxins in bulk materials or airborne dusts.

Endotoxins, a lipopolysaccharide substance produced by Gram-negative bacteria, were detected in all samples of barley, barley malt, and settled dust. Endotoxin concentrations in bulk materials ranged from 86 endotoxin units per milligram of dust EU/mg to a high of 951 EU/mg. The highest endotoxin concentration was measured in settled dust from elevator A. The endotoxin content of the two barley malt samples averaged 434 Eu/mg. The average endotoxin concentration from three 1993 barley crop samples was 136 EU/mg. The sample of 1992 crop barley had the lowest endotoxin concentration, 86 EU/mg. This sampling data demonstrates a presence of endotoxin in the 1993 barley and malt products and the potential for endotoxin exposures during the handling of these materials.

Concentrations of airborne total dust in both personal and area samples ranged from 0.5 mg/m³ to a high of 47.0 mg/m³. The four personal samples had a mean concentration of 10.9 mg/m³ with a standard deviation of 15.6. The two area samples had concentrations of 1.0 and 47.0 mg/m³ respectively. The highest dust concentration, 47.0 mg/m³, was measured in the basement of elevator G during cleanup operations; these operations involved using a high pressure air hose to clean dust from plant or elevator areas. Work activities during the day of sampling involved predominantly the cleaning of the plant and elevators by blowing and sweeping dusts; the highest personal dust measurement, 34 mg/m³ was collected from a worker involved in similar cleaning operations in elevator A. The particle size distribution data show that most of the airborne dust were inhalable but not of respirable size (respirable dusts are capable of penetrating to the gas exchange regions of the lung). The particle size distribution sample collected from the G-Elevator had a mass median aerodynamic diameter (MMAD) of approximately 21 with a geometric standard deviation (GSD) of approximately 3.1. The sample collected from the kiln area had a MMAD of 26 with a GSD of approximately 2.9. Approximately 10 percent or less of the airborne dust was in respirable size fraction, below 10 micrometers in aerodynamic diameter. This would suggest that most of the airborne dust from this work setting would be deposited in the head or upper airways.⁽⁷⁾

All workers wore disposable particulate respirators during work according to company policy. The current OSHA PEL for grain dust is 10 mg/m³ as a TWA. Both NIOSH and ACGIH recommend TWA exposures to grain dust be maintained below 4 mg/m³. The disposable type respirator used by workers has an assigned protection factor of 5 if properly fitted and fit tested for each worker.⁽³⁵⁾ (Note that assigned protection factor (APF) refers to the minimum anticipated level of respiratory protection that would be provided by a properly

functioning respirator or class of respirators to properly fitted and trained users.) Assuming an APF of 5 for the disposable respirators, none of the personal exposures would have exceeded the OSHA PEL for grain dust. One of the personal exposures to grain dust would have exceeded both the ACGIH and NIOSH grain dust exposure criteria considering the exposed worker used a respirator with an APF of 5. A 5-fold reduction in this personal dust sample, (34 mg/m^3), would result in an exposure of 6.8 mg/m^3 . The improper use or fit of a respirator may result in a protection factor below 5 and increased worker exposure. Additionally, these grain dust standards may not be protective in instances where there is quantifiable mycotoxin contamination of the grain.

Concentrations of airborne endotoxins measured using both personal and area sampling ranged from $6,850 \text{ EU/m}^3$ to a high of $301,000 \text{ EU/m}^3$. The four personal samples had a mean of $58,700 \text{ EU/m}^3$ with a STD of 62,400. The two area samples had endotoxin concentrations of $13,500 \text{ EU/m}^3$ and $301,000 \text{ EU/m}^3$ respectively. The highest endotoxin (and dust) concentration was measured in the basement of elevator G during the cleanup operations described previously. These endotoxin exposures were reduced through the use of disposable particulate respirators; although, considering the high endotoxin concentrations in air, significant endotoxin exposure could still occur with the use of these types of respirators. As discussed previously, there are no OSHA, NIOSH, or ACGIH exposure standards or criteria for endotoxins. The lowest endotoxin exposure reported to cause adverse pulmonary response among subjects sensitive to cotton dusts was 90 EU/m^3 . Threshold endotoxin exposures among healthy human subjects are reported by Rylander as approximately $1,000$ to $2,000 \text{ EU/m}^3$ for an across-shift acute pulmonary response (decline in FEV_1) and 5000 to $10,000 \text{ EU/m}^3$ for fever.⁽³¹⁻³⁴⁾ Even with the potential reduction in exposure obtained by using a disposable respirator, endotoxin exposures from these dust blowing and sweeping operations would still be high in comparison to existing threshold exposure estimates.

Mycotoxin concentrations were not assayed in airborne dust samples. The mass of airborne dust collected did not permit quantification of trichothecene mycotoxins considering the sensitivity of the analytical methods used.

VIII. CONCLUSIONS

Viable fungi were cultured in all barley, malt, and dust samples; fungi of the *Fusarium* genus were the most abundant in most of the 1993 barley and dust samples. The trichothecene mycotoxins deoxynivalenol and 15 acetyl-DON were detected in 1993 barley samples. Trichothecene mycotoxins were not detected in the sample of 1992 barley believed to have been grown and harvested under dryer conditions. Deoxynivalenol, the most abundant trichothecene mycotoxin detected in the samples, was also detected in samples of settled dust indicating the potential for aerosolization of mycotoxins and worker exposure.

The plant operations sampled during the survey were worse-case scenario including the cleaning of both the elevators and the plant by blowing and sweeping dusts. This is not the routine work activity and likely increased airborne dust and endotoxin concentrations. Some of the personal and area samples for airborne grain dust were high by comparison to existing exposure standards and criteria of OSHA, NIOSH, AND ACGIH; although, all workers sampled used respiratory protection to reduce these exposures. The highest grain dust concentrations were measured during blow down cleaning operations in the grain elevators G and A. All of the personal and area samples for endotoxin concentrations in air were high by comparison to estimated human thresholds for respiratory response. The type of respirator used by workers (the disposable particulate respirator) would not have an adequate protection factor to prevent overexposure to some of the higher dust concentrations and the endotoxins concentrations in air.

Although no acute febrile illnesses were identified while NIOSH was on site, the environmental sampling indicated a potential for overexposure to organic dust and mycotoxin. The most frequently reported complaint, by more than 1/3 of the participants, was for eye irritation.

IX. RECOMMENDATIONS

1. Workers should be knowledgeable of the respiratory health hazards posed by overexposure to organic dusts and aware of symptoms that can accompany overexposure. Please refer to the NIOSH Alert on Preventing Organic Dust Toxic Syndrome as a resource.⁽³⁶⁾ Workers with respiratory illness that they associate with exposures to grain dust should be referred for medical evaluation.

2. Care should be taken to ensure that the harvest and storage of agricultural products is done in a manner to minimize spoilage and microbiological contamination.
3. Workers involved in handling barley or malt that has become highly contaminated with molds and with detectable levels of mycotoxins (e.g., trichothecene mycotoxins) should be protected from overexposures through the use of engineering controls such as local exhaust ventilation. In instances where the work activity is not amenable to control by engineering methods, or during interim periods of process change (e.g., ventilation system installation), appropriate respiratory protection should be used to prevent worker overexposure.
4. Respiratory protection should be used as part of a formal, written respiratory protection program. Care should be taken in selecting an appropriate type of respirator. The NIOSH recommendation is for a minimum level of respiratory protection equal to the disposable N95 filter respirator certified by NIOSH (42 CFR 84). High efficiency particulate filter (HEPA) respirators certified by MSHA/NIOSH under 30 CFR 11 or other N, P, or R filter respirators certified by NIOSH under 42 CFR 84 could also be selected. The respirators selected should have an APF sufficient to protect workers from the airborne contaminant concentrations present in the work setting. Different levels of respiratory protection may be required for high exposure tasks such as the blowing or sweeping of dusts during cleaning operations.
5. Workers should be provided appropriate personal protective equipment (PPE) to prevent skin and eye contact with bulk materials that have become contaminated with mycotoxins.
6. To reduce airborne dust concentrations and exposures during cleaning operations, consider the use of vacuum cleaning as opposed to the blowing of settled and bulk dusts. Vacuum systems with HEPA filters have been shown to be very effective in reducing respirable dust concentrations.

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XII. DISTRIBUTION AND AVAILABILITY OF REPORT

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1. Confidential Requestors
2. Ladish Malting Inc.
3. Allied Industrial Workers of America, International Union
4. Brewers and Maltsters, D.A.L.U. 53, AFL-CIO
5. Occupational Safety and Health Administration, Region V

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

TABLE 1. SAMPLING METHODS
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

ANALYTE	MEDIA & SAMPLER	LITERS / MINUT E	ANALYTICAL METHODS
Total Dust in Air	37 mm mixed copolymer filter in a open face filter cassette	4.0	Gravimetric analysis ⁽⁵⁻⁷⁾ Endotoxins by LAL test ⁽⁴⁾
Respirable Dust in Air	37 mm mixed copolymer filter in line with a 10 mm nylon cyclone	1.7	Gravimetric analysis ⁽⁵⁻⁷⁾
Airborne Particle Size Distributions	Grease coated mylar filter media in a six stage cascade impactor	2.0	Gravimetric analysis ⁽⁵⁻⁷⁾
Fungi in Air	25 mm Polycarbonate filters in open face total dust cassettes	2.0	Identification of fungi by dilution plating on nutrient agar, incubation, and colony counts ⁽⁸⁻¹²⁾

TABLE 2
FUNGAL GENERA IDENTIFIED IN BULK AND AIR SAMPLES
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

SAMPLE TYPE	LOCATION	FUNGAL GENERA¹
Bulk Barley	Barley Elevator G-19	Yeast, <i>Fusarium</i> , Cladosporium, Bipolaris, Phoma, Epicoccu, Alternaria, Aspergillus glaucus.
Bulk Barley	Barley Elevator G-23	Yeast, <i>Fusarium</i> , Cladosporium, Penicillium, Alternaria.
Bulk Barley	Barley Elevator G-34	Yeast, Cladosporium, Penicillium, Alternaria, Epicoccum.
Bulk Barley	Barley Elevator G-10 (Control - 1992 Crop)	Yeast, Alternaria, Epicoccum, Cladosporium, Phoma.
Bulk Malt	Malt Kiln 12, Lower Level	Yeast, Alternaria, Aspergillus glaucus.
Bulk Malt	Malt Kiln 12, Upper Level	Yeast, Alternaria, Cladosporium.
Settled Dust	A Elevator	Yeast, Phoma, <i>Fusarium</i> , Epicoccum, Bipolaris, Aspergillus, Aspergillus glaucus, Alternaria, Cladosporium.
Total Airborne Dust	Barley Elevator G - Lower Level during Sanitation	Yeast, Penicillium, <i>Fusarium</i> , Cladosporium, Alternaria, Wallemia.
Total Airborne Dust	Malt Kilns 5 & 10 Kiln Cleaner Area	Cladosporium, Yeast, Mucor, Wallemia, Absidia, Penicillium, Aspergillus Flavus.

¹ - Fungal genera are listed in the order of relative abundance of colonies present in the sample.

TABLE 3
TRICHOHECENE MYCOTOXIN CONCENTRATIONS IN BULK SAMPLES
CONCENTRATIONS IN PPM
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

CONCENTRATIONS BY SAMPLING LOCATIONS

TRICHOHECENE MYCOTOXINS	MINIMUM DETECTABLE CONCENTRATIONS	BARLEY ELEVATORS				MALT KILN 12	SETTLED DUST	
		G-10	G-19	G-23	G-34		G ELEVATOR	A ELEVATOR
T-2 Toxin	0.125	ND	ND	ND	ND	ND	ND	ND
HT-2 Toxin	0.225	ND	ND	ND	ND	ND	ND	ND
Diacetoxyscirpenol	0.75	ND	ND	ND	ND	ND	ND	ND
Neosolaniol	0.75	ND	ND	ND	ND	ND	ND	ND
Fusarenon-X	0.5	ND	ND	ND	ND	ND	ND	ND
Deoxynivalenol	0.125	ND	6.5	6.0	2.6	ND	0.8	2.5
Nivalenol	0.5	ND	ND	ND	ND	ND	ND	ND
Zearalenone	0.1	ND	ND	ND	ND	ND	ND	ND
Zearalenol	0.3	ND	ND	ND	ND	ND	ND	ND
15 acetyl-DON	0.125	ND	0.6	0.5	0.2	ND	ND	ND
3 acetyl-DON	0.125	ND	ND	ND	ND	ND	ND	ND

PPM - Concentrations in parts per million parts (PPM) by weight.

ND - Refers to samples below the minimum detectable concentration.

TABLE 4
ENDOTOXIN CONCENTRATIONS IN BULK SAMPLES
CONCENTRATIONS IN EU/mg
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

SAMPLE TYPE	LOCATION	ENDOTOXIN CONCENTRATION EU/mg
Bulk Barley	Barley Elevator G-19	194
Bulk Barley	Barley Elevator G-23	127
Bulk Barley	Barley Elevator G-34	87.0
Bulk Barley	Barley Elevator G-10 (Control - 1992 Crop)	86.0
Bulk Malt	Malt Kiln 12, Lower Level	302
Bulk Malt	Malt Kiln 12, Upper Level	567
Settled Dust	A Elevator	951

EU/mg - Concentrations in endotoxin units per milligram of dust (EU/mg).

TABLE 5
TOTAL DUST AND ENDOTOXIN CONCENTRATIONS IN AIR CONCENTRATION¹
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

SAMPLE	SAMPLE TYPE	JOB OR AREA	DUST (mg/m³)	ENDOTOXIN (EU/m³)
21937	Personal*	Sanitation (G Elevator)	6.2	19,200
21932	Personal*	Kiln Elevator OP	0.5	6,850
21930	Personal*	Kiln Dumper	2.9	64,300
21927	Personal*	Sanitation (A Elevator)	34.0	145,000
21929	Area	G Elevator Basement	47.0	301,000
21931	Area	Kiln #5 and 15 Area	1.0	13,500

¹Concentrations reported in milligrams per cubic meter of air (mg/m³) for total dust and endotoxin units per cubic meter of air (EU/m³) for endotoxins.
* According to company policy, each worker was required to use a disposable respirator when working with barley believed to contain mycotoxins.

TABLE 6
MEAN CONCENTRATIONS OF TOTAL DUST AND ENDOTOXIN IN AIR
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

SAMPLE TYPE	SAMPLES	MEAN	STD	RANGE	
				LOW	HIGH
TOTAL DUST - PERSONAL SAMPLES	4	10.9	15.6	0.5	34.0
TOTAL DUST - AREA SAMPLES	2	24.0	32.5	1.0	47.0
TOTAL ENDOTOXIN - PERSONAL SAMPLES	4	58,700	62,400	6,850	145,000
TOTAL ENDOTOXIN - AREA SAMPLES	2	157,000	203,100	13,500	301,000

Concentrations reported in milligrams per cubic meter of air (mg/m³) for total dust and endotoxin units per cubic meter of air (EU/m³) for endotoxins.

TABLE 7
PREVALENCE OF BASELINE SYMPTOMS REPORTED TO BE WORK-RELATED
Ladish Malting Co.
Jefferson, Wisconsin
HETA 94-0033-2552

	Cigarette Smoking History							
	Current (N=6)		Former (N=7)		Never (N=8)		All (N=21)	
	N	%	N	%	N	%	N	%
Chest Symptoms								
Dry cough	2	33	0	0	1	12	3	14
Cough with phlegm	1	17	3	43	1	12	5	24
Wheezing chest	1	17	1	14	0	0	2	10
Chest tightness	1	17	1	14	0	0	2	10
Dyspnea	0	0	0	0	0	0	0	0
Breathlessness	1	17	1	14	0	0	2	10
Nasal irritation	0	0	0	0	0	0	0	0
Throat irritation	1	17	1	14	1	12	3	14
Sinus trouble	2	33	0	0	0	0	2	10
General Symptoms								
Fever	0	0	0	0	0	0	0	0
Headache	2	33	0	0	0	0	2	10
Vertigo	0	0	0	0	0	0	0	0
Nausea	0	0	0	0	0	0	0	0
Tiredness	0	0	0	0	0	0	0	0
Joint pains	1	17	0	0	0	0	1	5
Skin problems	0	0	0	0	1	12	1	5
Eye irritation	4	67	1	14	3	38	8	38

TABLE 8
PREVALENCE OF SYMPTOMS WITHIN 24 HOURS AFTER THE START OF THE WORK SHIFT
Ladish Malting Co., Jefferson, Wisconsin
HETA 94-0033-2552

	Cigarette Smoking History							
	Current (N=6)		Former (N=7)		Never (N=8)		All (N=21)	
	N	%	N	%	N	%	N	%
Chest Symptoms								
Dry cough	1	17	0	0	1	12	2	10
Cough with phlegm	0	0	1	14	2	25	3	14
Wheezing chest	0	0	0	0	0	0	0	0
Chest tightness	0	0	1	14	0	0	1	5
Dyspnea	0	0	0	0	0	0	0	0
Breathlessness	2	33	0	0	0	0	2	10
Nasal irritation	0	0	0	0	0	0	0	0
Throat irritation	2	33	1	14	2	25	5	24
Sinus trouble	1	17	0	0	2	25	3	14
General Symptoms								
Fever	0	0	1	14	0	0	1	5
Headache	1	17	0	0	1	12	2	10
Vertigo	0	0	0	0	0	0	0	0
Nausea	0	0	0	0	1	12	1	5
Tiredness	2	33	2	29	3	38	7	33
Joint pains	0	0	0	0	1	12	1	5
Skin problems	0	0	0	0	1	12	1	5
Eye irritation	3	50	1	14	4	50	8	38