HETA 98-0072-2762
Allgrind Plastics, Inc.
West Portal, NJ

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PREFACE

The Respiratory Disease Hazard Evaluations and Technical Assistance Program (RDHETAP) of the National Institute for Occupational Safety and Health (NIOSH) Division of Respiratory Disease Studies (DRDS) conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

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ACKNOWLEDGMENTS AND AVAILABILITY OF REPORT

This report was prepared by David Weissman, MD, and Chris Piacitelli, MS, CIH, of the RDHETAP, and Donald P. Schill, MS, CIH, of the New Jersey Department of Health and Senior Services (NJDHSS). Field assistance was provided by Gina Buono, MD, former DRDS Medical Officer and Michael Coyne, MS, CIH, of the NJDHSS. Analytical support was provided by Daniel M. Lewis, PhD, Paul D. Siegel, PhD, and Mike P. Whitmer of DRDS. Desktop publishing was performed by Terry L. Rooney.

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Health Hazard Evaluation Report 98-0072-2762
Allgrind Plastics, Inc.
West Portal, NJ
June, 1999

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SUMMARY

In January 1998, the State of New Jersey, Department of Health and Senior Services (NJDHSS), requested technical assistance from the National Institute for Occupational Safety and Health (NIOSH) in investigating a possible health hazard at the Allgrind Plastics, Inc., milling facility in West Portal, New Jersey. Allgrind Plastics is primarily engaged in size reduction of various plastics using attrition mills, knife mills, and hammer mills. In general, the company does many small jobs and thus over time has processed many types of plastics. Within the last few years, the company has also been processing organic materials, primarily shark cartilage, into fine powders for use as natural remedies for various diseases. The request was prompted by the death of a 38-year-old employee of an acute asthma attack while at work on April 19, 1997. Prior to his death, the employee had attributed acute asthmatic symptoms to shark cartilage dust on a number of occasions.

On May 26-28, 1998, an industrial hygienist and two medical officers from NIOSH, and an industrial hygienist from the NJDHSS, visited Allgrind Plastics. They conducted a walk-through evaluation of the plant, met with all current workers, and reviewed pertinent company records. Subsequent to the visit, former employees were contacted by telephone and questioned regarding work-related symptoms. Also, bulk samples collected at the worksite underwent laboratory analysis. In addition to the site visit noted above, personnel from the NJDHSS conducted a prior site visit on November 14, 1997, and conducted industrial hygiene evaluations, with air sampling of selected processes, on March 12 and April 22, 1998.

Personal samples in the shark grinding areas measured 44.7 and 26.4 milligrams per cubic meter of air (mg/m^3)total dust and 5.14 and 0.92 mg/m^3 respirable dust on March 12, 1998. During the sampling on April 22, 1998, the personal samples measured 12.3 mg/m^3 total dust and 1.97 mg/m^3 respirable dust, and concentrations of 2.94 mg/m^3 total dust and 0.34 mg/m^3 respirable dust were measured on samplers worn by an operator milling plastic. Area samples for total dust did not exceed 0.43 mg/m^3, and area respirable dust samples remained below 0.24 mg/m^3 during both days of sampling by NJDHSS. Endotoxin concentrations of bulk samples of shark cartilage did not exceed 1.6 endotoxin units per milligram (EU/mg).

It was found that unique exposures exist at Allgrind Plastics due to the production of dusts from materials not normally inhaled. Air monitoring showed that certain processes generated significant airborne concentrations of these dusts. Limited medical experience exists to predict the health effects of many of these dusts after inhalation. However, medical findings noted during the May 1998 site visit were consistent with a significant burden of work-associated respiratory symptoms in current and former workers, many of them irritative in nature. In addition, three workers were identified as being likely to have developed true occupational asthma after working at Allgrind Plastics

for a period of months to years. An additional worker was identified with urticaria and angioedema induced by a material in the workplace (ethylene diamine acid phosphate). These findings strongly suggest that a sensitizing substance or substances are present in the workplace and capable of inducing disease.

Two materials were identified as particular problems by workers. Shark cartilage dust was the material most frequently identified as troublesome by current and former workers. Ethylene diamine acid phosphate was the second most frequently cited material. Dusts of both appear to be irritating. Ethylene diamine is a well documented sensitizer and has been reported to cause asthma. Shark cartilage has not previously been reported to cause immunologic sensitization but in theory it could. Although dusts generated from both of these materials are regulated under a "particulates, not otherwise classified or regulated (PNOC/R)" standard, this standard is likely not fully protective against the effects of poorly studied but potentially more injurious dusts such as those encountered here.

Various industrial hygiene measures are recommended to control dust exposures, not only to the respiratory tract but also to face, eyes, and skin. In addition, worker education, environmental monitoring, and medical surveillance measures are recommended for prevention of disease, as well as for early identification and prevention of disease progression.

NIOSH investigators conclude that dusts produced by industrial processes at Allgrind Plastics are a significant health hazard. Many workers have symptoms when exposed to these dusts. Several workers have developed asthma while working at the plant. Two materials, shark cartilage dust and ethylene diamine acid phosphate dust, appear to pose a significant health hazard. The "Recommendations" section of this report provides suggestions for ways to decrease problems caused by these dusts. These include ways to decrease exposure, worker education, ways to detect early illness, and what to do if a worker gets sick.

Keywords: SIC 3089 (plastics products, not elsewhere classified), SIC 2833 (Drug/Herb grinding, grading, and milling), asthma, urticaria, ethylene diamine acid phosphate, shark cartilage, particulates not otherwise classified or regulated (PNOC / PNOR).

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INTRODUCTION

In January 1998, the State of New Jersey, Department of Health and Senior Services (NJDHSS), requested technical assistance from the National Institute for Occupational Safety and Health (NIOSH) in investigating a possible health hazard at the Allgrind Plastics, Inc., milling facility in West Portal, New Jersey. Allgrind Plastics is primarily engaged in size reduction of various plastics using attrition mills, knife mills, and hammer mills. In general, the company does many small jobs and thus over time has processed many types of plastics. Within the last few years, the company has also been processing organic materials, primarily shark cartilage, into fine powders for use as natural remedies for various diseases. The request was prompted by the death of a 38-year-old employee of an acute asthma attack while at work on April 19, 1997. Prior to his death, the employee had attributed acute asthmatic symptoms to shark cartilage dust on a number of occasions.

On May 26-28, 1998, an industrial hygienist and two medical officers from NIOSH, as well as an industrial hygienist from NJDHSS, visited Allgrind Plastics. They conducted a walk-through evaluation of the plant, met with all current workers, and reviewed pertinent company records. Medical records of the deceased worker made available by the State of New Jersey were also reviewed. In addition, a bulk sample of shark vertebrae, to be used as source material for the preparation of powdered shark cartilage, was collected for analysis of endotoxin and protein content. Subsequent to the walk-through, these analyses were performed using this sample and a sample of shark cartilage powder milled at Allgrind Plastics and previously collected by NJDHSS. In addition, 9 former employees were contacted by telephone and questioned regarding work-related symptoms. Finally, personnel from NJDHSS had visited Allgrind Plastics on November 14, 1997, to meet with facility management and conduct an initial walk-through evaluation of the plant. NJDHSS personnel returned on March 12, 1998, and April 22, 1998, to collect personal breathing zone and area environmental air samples for respirable and total dusts.

Initial findings and recommendations were communicated to company personnel and an employee representative during the closing meeting on May 28, 1998. This final report serves to summarize the activities, observations, and findings and closes this evaluation.

BACKGROUND

Allgrind Plastics consists of two largely single level buildings connected by a breeze way to form a "U" shaped plant. The building referred to as "A-Building" is the site of the main plant entrance, offices, and in the plant itself, storage areas, various mills, blenders, and a compressed air room. It is used primarily for processing of plastic products, which has been the main activity of this company for a number of years. Adjacent areas of the second building are referred to by plant management as "B-Building" and "C-Building" (although these are actually areas of a single building separated by a partial wall). B-Building is the site for several storage areas, mills, a sifter, and a "test mill" area. Shark cartilage is currently ground only in C-Building. It contains several storage areas, an enclosed area where shark cartilage is ground (referred to in this report as "System #1"), and an open area where shark cartilage is ground (referred to in this report as "System #2"). Each shark cartilage grinding system is made up of several mills. One worker operates each system. Processing of shark cartilage from primary materials (skulls, vertebrae, etc.) into powder for use as a natural remedy for a variety of diseases is a relatively new activity for this business and has only been done since late 1995.

Shark cartilage powder is sold for use as a remedy for a variety of health conditions, such as cancer, arthritis, psoriasis, diabetic retinopathy, and other chronic conditions. According to one source, approximately 250,000 pounds per year of shark cartilage material is processed in New Jersey and two

million pounds per year nationwide. There are approximately 14 companies in the United States that process raw shark cartilage material into powder; and at least three of the companies are located in New Jersey. There are four main steps to processing shark cartilage: 1) Cleaning, 2) Drying, 3) Pulverizing, and 4) Sterilizing. Allgrind Plastics is involved in the third step of the process; that is, pulverizing the cleaned and dried cartilage material into powder.

Raw shark cartilage is typically received in boxes that contain cleaned vertebrae and/or vertebral column segments. At times, shark skulls and/or fins are also processed into powder. The boxes are cut open by the operator and dumped onto a platform attached to the mill. As it is dumped, the shark material is pushed into the feed chute of the mill.

In both System #1 and System #2, the material is pulverized into a fine powder. The processing of the material into the desired powder size involves milling and cycling the powder through a series of mesh screens. The final screen ensures that powder of the required mesh size (ranging from 80 to 325 mesh, depending on client requirements) is collected. The product is released into a tube fitted with a gate valve that is connected to a lid covering a fiberboard packing drum. When the drum is nearly full of product, the operator closes the gate valve, removes the lid, and drags the drum to a nearby weigh station. There, the packing drum is lifted onto a scale, and the weight is adjusted by adding or removing product. Another drum containing the final product is located at the weigh station. When the weight of the drum is too low, the operator uses a scoop to add product to the drum. Conversely, when the weight of the packed drum is too high, the operator removes product using the scoop and transfers it to the adjacent drum. Once the desired weight is achieved, typically 162 pounds, a lid is affixed to the drum top with a metal tension-band seal. The packed drum is then moved to a pallet and transferred by forklift to a location where it is stored until shipment.

The deceased employee whose death lead to this investigation first sought medical attention for respiratory symptoms he attributed to grinding shark cartilage on November 17, 1995. He was noted at the time to be wheezing. Subsequent symptomatic attacks consistent with acute asthma and attributed to shark cartilage exposure lead to medical visits on September 16, 1996; October 16, 1996; October 18, 1996 (seen at ER); March 11, 1997; March 27, 1997 (seen at ER); and April 4, 1997. At some point during this time, he was removed from grinding operations and assigned other duties. However, he continued to have problems with asthma at work that he personally attributed to inhalation exposures to shark cartilage dust. On April 19, 1997, he had a fatal attack of status asthmaticus while at work. Autopsy confirmed the cause of death as acute asthma.

Prior to the NIOSH walk-through visit of May 1998, Allgrind Plastics had been visited by the New Jersey Department of Labor (NJDOL) On-Site Consultation Service for measurement of total airborne dust levels and by industrial hygienists from NJDHSS. A report from the NJDOL On-Site Consultation Service dated May 29, 1997 noted the following 8-hour time-weighted average (TWA) total airborne dust levels: personal sampling in the shark cartilage grinding area - 28.0 mg/m^3; area sampling of the shark cartilage grinding area - 2.0 mg/m^3; personal sampling in two plastic processing areas - 1.3 mg/m^3 and 0.83 mg/m^3. Comment is made that exposure levels "represent...almost a 50% reduction when compared to their initial monitoring for dust exposure." Another personal sample collected on August 14, 1997, on an operator during grinding of shark cartilage measured 14.1 mg/m^3. The OSHA permissible exposure limit (PEL) that was applied to these exposures was the 8-hour TWA of 15 mg/m^3 for total airborne dust as particulate, not otherwise regulated (PNOR). Industrial hygienists from the NJDHSS conducted a site visit at Allgrind Plastics on November 14, 1997. Although shark cartilage processing was not underway at the time, settled dust was noted on and around machinery suggesting that exposures were possibly occurring during processing operations. Observation of active plastic grinding operations also suggested that dust exposure was occurring.

METHODS

Environmental Evaluation

A walk-through survey of the plant was conducted by personnel from NJDHSS on November 14, 1997. Air sampling was conducted by NJDHSS industrial hygienists on March 12, 1998 and April 22, 1998. On May 27-28, 1998, a NIOSH industrial hygienist joined a NJDHSS industrial hygienist on a walk-through survey of the plant.

During air sampling, total dust samples were collected in accordance with NIOSH Method 0500. They were collected on pre-weighed, 37-millimeter (mm) diameter, 5-micrometer (µm) pore size, polyvinyl chloride (PVC) membrane filters. Samples were analyzed by a laboratory accredited by the American Industrial Hygiene Association (AIHA). Mass gain of total dust was measured gravimetrically.

Respirable dust samples were collected in accordance with NIOSH Method 0600. They were collected on pre-weighed, 37-mm diameter, 5-µm pore size, PVC membrane filters with 10-mm nylon cyclones as precollectors to ensure that only the respirable fraction of dust was collected on the filters. Samples were analyzed by a laboratory accredited by the AIHA. Mass gain of respirable dust was measured gravimetrically.

On March 12, 1998, air samples were collected as follows:

1) Personal - Operator of System #1: respirable and total dust samples.
2) Personal - Operator of System #2: respirable and total dust samples.
3) Area - Approximately 8 feet south of System #2: respirable and total dust samples.
4) Area - At Weigh Station of System #2: respirable dust sample.

On April 22, 1998, air samples were collected as follows:

1) Personal - Operator of System #1: respirable and total dust samples.
2) Area - On the table outside of the mill rooms of System #1: respirable and total dust samples.
3) Personal - Operator of the SE-1 Mill: respirable and total dust samples.
   Note: System #2 was not running on the day of sampling. Therefore, samples were collected at a mill that was processing plastic material.

During the walk-through survey of May 27, 1998, a sample of source material (vertebrae) for production of powdered shark cartilage was collected for assessment of endotoxin and total nitrogen content. The sample was transported to NIOSH (Morgantown, WV) under ambient conditions. After arrival, the sample was saved at -20° Centigrade until processing. The sample was wrapped in aluminum foil, fragmented into large pieces by pounding with a hammer, and then pulverized into powder in a ball mill. Processing components of the mill, as well as aluminum foil, were baked to remove endotoxin prior to use. Three aliquots of the freshly ground powder were extracted at room temperature in sterile pyrogen-free water (BioWhittaker®, Walkerville, MD) for one hour with constant mixing on a platform rocker. In addition to the freshly ground shark cartilage powder, 200-mesh shark cartilage powder ground on-site at Allgrind was collected by the NJDHSS directly from the mill and mailed under ambient conditions to NIOSH where it was saved at -20°C until 3 aliquots were extracted as noted for freshly ground powder.

Extract was assessed for endotoxin content using a chromogenic limulus amebocyte lysate assay kit (Kinetic QCL, BioWhittaker®, Walkerville, MD). Total nitrogen content was assessed using a pyrochemiluminescent nitrogen analyzer (Antex®, Houston, TX). Glycine was used as an external standard. The extract was also dialyzed with a 10,000 (10K) dalton molecular weight (MW) cut-off and analyzed as above after dialysis for nitrogen content due to presence of free amino acids, small peptides, and low MW substances (such as

epinephrine, acetylcholine etc). As nitrogen makes up 15 to 20% of amino acids, a conversion factor of 6.25 can be used to convert nitrogen content (associated with the fraction with MW greater than 10K daltons) to protein content.

Medical Evaluation

On May 26-28, 1998, two medical officers from NIOSH visited Allgrind Plastics. Initially, relevant on-site records were reviewed. The Occupational Safety and Health Administration (OSHA) log and summary of occupational injuries and illnesses (Form 200) from 1993 to the current date was reviewed for respiratory entries. Material Safety Data Sheets (MSDS) were reviewed for materials processed in the plant to assess for potential respiratory toxicities. In addition, on-site medical records were reviewed. Subsequently, all 17 current employees in the plant underwent medical interview to assess health and symptom status. Permission to review off-site records was sought as appropriate from symptomatic individuals. In addition, using payroll data from 1997 and 1998, previous employees during that period of time were identified. Payroll records provided only name and address, so in order to contact former employees by telephone for interview about health and symptom status when they worked at the plant, telephone numbers were obtained as possible from internet resources ("Whowhere"®, "Four11"®, and "Yahoo"®). Telephone numbers were obtained and interviews conducted for a total of 9 such individuals out of a possible total of 67 former employees.

EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for the 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, however, important to note that not all workers will be protected from adverse health effects even though their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the 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 Recommended Exposure Limits (RELs);[1] (2) the American Conference of Governmental Industrial Hygienists' (ACGIH®) Threshold Limit Values (TLVs®);[2] and (3) the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs).[3] NIOSH encourages employers to follow the OSHA limits, the NIOSH RELs, the ACGIH TLVs, or whichever are the more protective criterion. The OSHA PELs reflect the feasibility of controlling exposures in various industries where the agents are used, whereas NIOSH RELs are based primarily on concerns relating to the prevention of occupational disease. It should be noted when reviewing this report that employers are 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 higher exposures over the short-term.

Specific information regarding materials relevant to the current evaluation follows:

Particulates Not Otherwise Classified or Regulated

Many of the particulates generated by grinding and milling activities in this plant are among those currently regulated as particulates not otherwise classified or regulated (PNOC/R). These are dusts for which current evidence for toxicity is insufficient to justify a substance-specific exposure limit. However, an excessive concentration in workroom air even of nontoxic dust may reduce visibility and cause unpleasant accumulation in the eyes, ears, and nose, or trigger symptoms in susceptible individuals (e.g., asthmatics). The OSHA PEL for total particulate (not otherwise regulated) is a TWA of 15 milligrams per cubic meter of air (mg/m^3) for an 8-hour workday[3], and the ACGIH® TLV® for inhalable particulate (not otherwise classified)[2] is a TWA of 10 mg/m^3. The OSHA PEL for respirable particulate is 5 mg/m^3, and the ACGIH® TLV® is 3 mg/m^3.

Clearly, substances are processed at Allgrind Plastics for which evidence for inhalation toxicity is insufficient to specify an exposure limit, but which might pose a greater health risk than would be expected for relatively nontoxic dusts. One such material is solid ethylene diamine acid phosphate (CAS #14852-17-6). This substance constitutes 98% of a flame retardant frequently ground in the plant. Dust generated from this material is regulated under the PNOC/R standard. However, ethylene diamine in pure liquid or vapor form is a well known sensitizer capable of inducing both dermatitis and asthma.[2,4,5] Thus, the PNOC/R standard, which is intended to protect against relatively innocuous materials, may not be protective for exposure to solid phase ethylene diamine acid phosphate.

Organic materials such as shark cartilage might also contain bioactive or sensitizing components and pose a greater health hazard than dust generated from nontoxic materials. Again, even though such materials are regulated under the PNOC/R standard, adverse health effects might well occur at significantly lower levels than those specified in the standard.

Endotoxin

Endotoxin is a component of bacterial cell walls with inflammatory and irritant bioactivity. It is often a contaminant of organic materials and, when inhaled, can cause symptoms of upper and lower airway irritation, as well as systemic flu-like symptoms. Asthmatics are more sensitive to the airways effects of endotoxin than nonasthmatics. There are no occupational exposure criteria for airborne endotoxin. However, a recommended endotoxin exposure limit of 50 endotoxin units (EU)/m^3 based on inhalable dust sampling has recently been adopted in the Netherlands. This limit was established as about half of the 90 EU/m^3 level that induces measurable airways obstruction.[6]

RESULTS

Environmental

Walk-Through Evaluations

Records regarding types of materials ground and material safety data sheets (MSDSs) for these materials were reviewed. MSDSs were readily available from a station near the plant entrance. Over the previous several years, a large variety of materials had been processed in the plant including melamine, polyethylene, polyester, polyurethane, acrylic, polyvinyl chloride (PVC), polystyrene, Teflon, vinyl ester, ethylene diamine acid phosphate, cellulose, conathane rubber, silicone rubber, urea, shark cartilage, wax, walnut shells, shrimp shells, sea cucumber, sea shells, ginseng, valerian, dandelion, cat's claw, etc. Of note is that a product containing ethylene diamine was often processed for use as a flame retardant. Shark cartilage was, by a very large margin, the most commonly processed organic material.

During the walk-through survey of May 27, 1998, the A-Building was quite dusty, with visible dust on all surfaces, including ceiling beams. B-Building looked cleaner. C-Building was not in active use, but dust was noted on mills of System #2. System #1, an enclosed room dedicated to grinding of shark cartilage, was quite dusty. The room was noted to be unventilated.

With the exception of the System #1 area in C-Building, equipment was unenclosed. Machines were not generally equipped with local exhaust ventilation. Ground material from mills dropped into receptacles and some leakage was noted. It was noted in conversation that mill gasket connection failure was a frequently troublesome problem causing dust leakage. It was also noted that grinding of some plastic materials resulted in an "acrylic smell" that was distasteful to some individuals.

Cleanup of spills and settled dust on floors was routinely performed by means of dry sweeping with a push broom. Vacuum cleaners equipped with high efficiency particulate air (HEPA) filters were readily available, and were mainly used for cleaning up small amounts of dust contamination. NJDHSS personnel observed one worker using compressed air to remove shark cartilage dust from his work clothing.

With regard to personal protective equipment (PPE), hearing protection was required but safety glasses were not. Respirators were made available to all workers, but respirators or dust masks were mandatory only for operators of the Tandom (a type of mill), blenders, or for milling of shark cartilage. In the unventilated System #1 room, respirators were the primary means of exposure control. The system operator wears a 3M 7000® series half-mask dual-cartridge respirator fitted with 3M 2091® P100 particulate filters. Another system operator wore a disposable particulate respirator while processing shark cartilage. A powered air-purifying respirator had been made available, in the past, to a worker with complaints of respiratory problems. Baseline and annual spirometry were provided by Allgrind Plastics' occupational medicine consultants. Fit testing was done either by the occupational medicine consultant in his office or on-site. A written respiratory protection program was being developed at the time of the NIOSH site visit.

Air Sampling and Observations Related to Air Sampling Visits

Air sampling results for March 12, 1998, and April 22, 1998, are presented in Tables 1 and 2, respectively. Personal samples in the shark grinding areas measured 44.7 and 26.4 mg/m^3 total dust and 5.14 and 0.92 mg/m^3 respirable dust on the first day of sampling. During the second visit (Table 2), the personal samples measured 12.3 mg/m^3 total dust and 1.97 mg/m^3 respirable dust. Concentrations of 2.94 mg/m^3 total dust and 0.34 mg/m^3 respirable dust were measured on samplers worn by an operator milling plastic on April 22, 1998. Area samples for total dust did not exceed 0.43 mg/m^3, and area respirable dust samples remained below 0.24 mg/m^3 during the two visits by NJDHSS.

The result of total dust sampling for the operator of System #1 was 298% of the OSHA PEL for PNOC/R of 15 mg/m^3 for March 12, 1998, and 82% of the PEL on April 22, 1998. The result of respirable dust sampling for the operator of System #1 was 103% of the OSHA PEL for respirable PNOC/R of 5 mg/m^3 (171% of the ACGIH® TLV® of 3 mg/m^3) for March 12, 1998, and 39% of the PEL (66% of the TLV®) on April 22, 1998. The result of total dust sampling for the operator of System #2 was 176% of the OSHA PEL for March 12, 1998. The result of respirable dust sampling for the operator of System #2 was 18% of the OSHA PEL (31% of the ACGIH® TLV®) for March 12, 1998.

There were several observed sources of dust generation associated with the shark cartilage processing systems and the work practices of system operators:

1) Loading of raw shark cartilage material into the mill.
2) Leaks at seams and bolt holes of the mill housing.
3) The feed hopper of the mill.

4) Leaks at seams and bolt holes of the mill housing.
5) Leaks at seams and damaged areas of the ducts involved with the movement of pulverized material within the milling systems.
6) Floor level vent on System #2.
7) Damaged and/or failed felt gaskets of the screening frames.
8) Manual feeding of material into the feed hopper of the mill.
9) Lid removal from drums, after filling.
10) Adjustment of the filled drum's weight, using a scoop.
11) Use of a broom for dry sweeping of spills and settled dust.
12) Use of compressed air to remove dust from work clothing.

The results of sampling indicate that there are significant potential exposures to dusts for the operators of both shark cartilage processing systems. The most significant sources of dust generation observed during air sampling were: the failure of a screen frame gasket on System #1 on March 12, 1998; the manual feeding of the feed hopper on System #2 on March 12, 1998; and the adjustment of drum weight using a scoop at both systems on both sampling dates.

Extractable Endotoxin and Nitrogen Content of Shark Cartilage Samples

Extractable endotoxin content of shark cartilage samples is presented in Table 3. All analyses from the two samples demonstrated low endotoxin content, which in all cases was less than 1.6 EU/mg dust.

Extractable total nitrogen of shark cartilage dust samples is also shown in Table 3. Total extractable nitrogen content of the freshly ground and factory prepared dust samples was quite similar with a slightly higher content from the freshly ground samples. Total nitrogen reflects proteins as well as smaller species such as free amino acids, small peptides, and other low molecular weight (MW) substances such as epinephrine, acetylcholine, etc. The larger MW species profile was quite different between the freshly ground and factory prepared samples. Of the freshly ground sample extractable nitrogen, 97% was from greater than 10K dalton MW species (i.e., proteins). The 200 mesh (factory prepared) samples were quite variable with 13 to 89% of the nitrogen being associated with species of MW greater than 10K daltons. This may be reflective of storage conditions, different source material, or harsher grinding of the factory sample. Of note is that, for the freshly ground shark cartilage, a significant amount of protein (using a conversion factor of 6.25 - about 100 micrograms of protein per milligram of shark cartilage powder) could be extracted from the shark cartilage in water. The presence of significant quantities of potentially soluble protein within ground shark cartilage powder suggests potential for sensitization or other biological effects.

Medical

Occupational Safety and Health Administration (OSHA) logs and summaries of occupational injuries and illnesses (Form 200) from 1993 to the current date were reviewed for respiratory entries. No respiratory entries were noted in the years 1993-1996. Fourteen entries involving nine workers were noted in 1997. Only one of these workers remained with the company at the time of review (May 26, 1998). One entry was noted for 1998 up to the date of review. Problems noted on the entries included chest pain, chest tightness, breathing trouble, and "dust reaction."

At the time of the visit, it was noted that as a result of slow business a number of workers had been laid off and the number of shifts the plant was operating had decreased. As a result of this, the company currently employed 17 workers, a decrease from previous times. Twenty-four additional former workers were noted to have been with the plant in 1998, and forty-three additional former employees in 1997. Of the 17 current employees, one was primarily an office employee and the remaining 16 engaged in labor in the plant itself. Of these 16 individuals, seven were

relatively recently employed and had been with the plant for six months or less.

All 17 current employees were interviewed. Seven noted that they suffered from work-associated symptomatology. All seven complained of chest symptoms such as chest tightness, wheeze, shortness of breath, or cough. In addition, five noted nasal or sinus symptoms, primarily stuffiness, dryness, burning, etc. Of note is that one of these employees had suffered from pollen allergies and felt that symptoms triggered by shark cartilage dust were quite different and distinguishable from those induced by pollen. Three current employees noted work-associated systemic symptoms such as fatigue or flu-like symptoms. In general, these symptoms improved on weekends away from work. In terms of materials triggering symptoms, six of the employees identified grinding of shark cartilage as a trigger. Four of the employees identified processing of ethylene diamine acid phosphate (variously referred to as Allbright & Wilson, Amgard NK® and NP®, and Antiblaze®) as an important, sometimes the most important, trigger of symptoms. One employee each identified "polyester" and "counter top material" as problems.

Based on review of OSHA logs and interviews of current employees, focused review of employee health records was performed. It was determined that, counting the deceased employee, three individuals with doctor-diagnosed asthma and histories of work-related exacerbation could be identified. In all three cases, onset of asthma occurred months to years after starting work in the plant. In addition, one individual was identified with doctor-diagnosed urticaria and angioedema induced by exposure to "Amgard" (ethylene diamine acid phosphate).

Phone numbers for nine former employees present on the 1997 and 1998 payrolls were obtained and the former employees interviewed. Six of the nine former employees had worked at the plant for a total duration of six months or less. Eight of the nine former employees noted work-related symptoms of some type. This prevalence rate (8/9) was significantly greater than the prevalence rate noted in current workers (7/17) ($p < 0.05$, Fisher Exact Test). Six of the eight symptomatic former employees noted chest symptoms, four of eight had nasal or sinus symptoms, and two of eight noted work-associated systemic symptoms. From the standpoint of triggers for symptoms, five of the eight symptomatic former workers identified shark cartilage dust, three simply noted that "dust" was a trigger, two noted Teflon, and one each noted acrylic and melamine as problems. Six of the eight symptomatic former employees were questioned with regard to latency period between first working in the plant and development of symptoms. Three of these individuals developed their symptoms within days of working in the plant, one in two weeks, and two "over time."

Medical surveillance activities were discussed with company personnel and with the occupational medicine consultant providing services to the company. For the past several years, all workers have had baseline medical evaluation including spirometry. Subsequently, spirometry and audiometry are performed annually. In order to be qualified for respirator use, workers must meet spirometric performance standards.

DISCUSSION

Allgrind Plastics represents an unusual situation with many unique exposures due to the nature of the work done there. Size reduction of the many materials processed, usually by milling, produces dusts of materials not normally inhaled. Thus, for many of the inhalation exposures, only limited medical experience exists. However, medical findings noted during the site visit were consistent with a significant burden of work-associated respiratory symptoms and disease in current and former workers. In addition, work-related symptoms appeared to be associated with a "healthy worker effect" (disproportionate departure of symptomatic workers from the plant). Evidence supporting this included departures of most workers noted on OSHA logs to have respiratory problems and the very high proportion of respiratory symptoms among former employees who we were able to

contact. Finally, information collected is compatible with three workers having developed true occupational asthma after working at Allgrind Plastics for a period of months to years. This finding is suggestive that *in these three workers* asthma was induced by immunologic sensitization to a substance in the workplace.[5]

Current workers, *including those without asthma*, identified two materials as perceived causes of respiratory symptoms. Shark cartilage dust was the material most frequently identified as causing respiratory symptoms. Most of the workers questioned noted minimal to no latency period between first exposure to this dust and development of respiratory symptoms such as chest pain, chest tightness, shortness of breath, etc. Lack of a latency period suggests that, *for most workers*, shark cartilage did not exert its effects via immunologic sensitization, as has been reported in fish processing plants.[7] In this regard, computer literature searches did not document a single reported case of shark allergy in the medical literature. Rather, lack of latency suggested some direct irritative or inflammatory effect of the shark cartilage dust that did not require immune sensitization was the relevant process in most workers. Shark cartilage contains potentially bioactive substances. Shark cartilage has been touted to have bioactivity as a potential anti-neoplastic agent, although this is controversial. Bioactivity is also suggested by the toxicities of orally administered preparations such as GI toxicity.[8] Findings suggestive of respiratory tract irritation do not rule out the possibility that individuals could become sensitized and develop true IgE-mediated allergies to shark cartilage. The finding that up to 10% of freshly ground shark cartilage could be extracted as protein after a 1 hour incubation in water suggests that the material has the potential to be allergenic. However, symptoms suggestive of IgE-sensitization to shark cartilage were not apparent among workers currently employed at Allgrind Plastics at the time of the site evaluation.

Because of the way in which shark cartilage was reported to have been separated from shark flesh (allowing dead animals to rot and then picking dried fleshy remains from the cartilaginous structures) endotoxin contamination was suspected as a potential source of irritative potential. However, measurement of extractable endotoxin suggested that levels of airborne endotoxin sufficient to induce symptoms would only be reached at the very highest total airborne dust concentrations measured in the plant.[6] Thus, although a possible cause of irritative symptoms under conditions of intense shark cartilage dust exposure, airborne endotoxin did not appear to be a primary cause of such symptoms. This does not rule out the possibility that other, more contaminated, batches of shark cartilage source material might contain enough endotoxin to trigger symptoms at lower concentrations of total airborne dust.

The second most frequently identified material by workers as causing respiratory symptoms was ethylene diamine acid phosphate. This solid material was frequently added to other plastics being ground as a flame retardant. Although toxicity of this particular solid material is not well documented, ethylene diamine is a well known irritant and sensitizer and has been reported to induce immunologically-mediated dermatitis and asthma.[2,4,5] Sensitization in the current setting is strongly suggested by induction of urticaria and angioedema by this material in a worker. Perhaps in view of these considerations, the MSDS for ethylene diamine acid phosphate notes its irritant and sensitizing potential and suggests "avoid generating dust." It also suggests that if dust is generated, local exhaust ventilation should be provided to meet the PNOC/R standard and a NIOSH approved particulate respirator used. Eye protection and impervious protective gloves and clothing are also recommended in order to avoid contact of this material with skin and eyes.

In addition to shark cartilage and ethylene diamine acid phosphate, several other materials with potential to induce respiratory symptoms and asthma were identified by review of MSDSs. One such group of materials are the epoxy resins. Both epoxy resins, and "hardeners" used to cross-link epoxy resins such as amines and anhydrides are capable of inducing sensitization and asthma.[5,9] A published case report suggests that grinding even a cured epoxy resin can

result in sensitization to the cross-linking hardener and lead to occupational asthma.[10] In a similar fashion, polymeric plastic products potentially containing unreacted formaldehyde, such as urea-formaldehyde and melamine formaldehyde, might have the potential to cause sensitization and asthma after grinding processes generate inhalable dust. Thus, PNOC/R limits, which are intended to limit exposures to nontoxic materials, are inappropriate to apply to exposures to toxic and bioreactive materials such as those encountered in this plant.

CONCLUSIONS

1) Work-related upper and lower respiratory tract symptoms were noted among current and former employees of Allgrind Plastics.

2) Many of the symptomatic employees identified dust resulting from grinding of shark cartilage and dust resulting from grinding of ethylene diamine acid phosphate as triggers for their symptoms. Both of these materials were identified by workers as irritating and both have potential for sensitization.

3) Inspection of the plant showed it to be fairly dusty. Air sampling conducted by the NJDHSS showed dust exposures well in excess of the established PNOC/R total and respirable dust standards. Use of engineering controls to control dust, such as machine enclosure and local exhaust ventilation, was limited. Use of PPE to control eye, skin, and respiratory contact was also limited. Some operator work practices were observed to contribute to excessive dust exposures.

4) Dust exposures encountered in this plant appear to have appreciable irritative and sensitizing potential. In view of this, PNOC/R limits, which are intended to regulate exposure to nontoxic materials without the potential to induce respiratory disease are inappropriate and are unlikely to be protective against work-associated respiratory symptoms and disease.

RECOMMENDATIONS

Continuing consultation with NJDHSS has resulted in measures being instituted to further reduce dust exposure, such as modifications to machinery and improvement in outside ventilation. In addition, the following recommendations are provided:

1) Eliminating, or substituting for, toxic substances: In many cases this will not be possible. Allgrind Plastics grinds source material provided by its customers, which is returned to customers for their use. Often, a toxic substance is a necessary ingredient of the customer's final product. However, MSDSs for source materials to be used should be reviewed. Where appropriate, if materials are identified as potentially hazardous, use of alternative less toxic substances should be explored.

2) Engineering Controls to Reduce Exposure: Where generation of dust is expected, process isolation, such as by enclosure, and local exhaust ventilation should be used to reduce exposures. The integrity of housings and ductwork of milling systems should be inspected regularly and maintained free of leaks. Investigate alternative gasket material for screen frames - one that is less prone to leakage and failure than the felt gaskets currently in use.

3) Work Practice Controls: Machine operators should be instructed and strongly encouraged to minimize the generation of airborne dust by their actions when transferring powders and other materials into drums and hoppers. Workers should be prohibited from dry sweeping to clean up dust and using compressed air to remove dust from clothing or other surfaces. HEPA-filtered vacuum cleaners should be used for these purposes.

4) Administrative Controls to Reduce Exposure: Areas where dust is generated should be restricted to workers who are essential to the process or operation.

5) Personal Protective Equipment (PPE):

   a) Because of the ability of substances such as ethylene diamine to induce sensitization by skin contact, workers exposed to such sensitizing substances should be protected from contact through the use of impervious protective clothing such as gloves, aprons, bodysuits, and protective footwear. Eyes and face should be protected using safety glasses with side shields, goggles, or face shields, as appropriate. Strong consideration should be given to the use of clothes or uniforms to be used only at work.

   b) The use of respirators is the least preferred method of controlling worker exposures. Respirators should not be used as the only control for routine operations. However, respirators may be necessary under certain conditions, such as if engineering controls are inadequately protective, during installation or repair of engineering controls, during spill cleanup, and during emergencies. NIOSH maintains that the most protective respirators should be used for situations involving carcinogens. NIOSH-approved respirators should be used as part of a comprehensive respiratory protection program. This program should include (1) regular training and medical evaluation of personnel; (2) fit testing; (3) periodic environmental monitoring; (4) periodic maintenance, inspection, and cleaning of equipment; (5) proper storage of equipment; and (6) written standard operating procedures governing the selection and use of respirators. The program should be evaluated regularly.

   c) In all cases, PPE (including respiratory protective equipment) should be donned and stored in a clean area away from production to avoid the risk of exposure and contamination of equipment.

6) Exposure Monitoring: Periodic monitoring should be conducted to document the effectiveness of engineering controls. Where available, documented exposure limits (usually available from MSDS) should guide evaluations. Because of the unique nature of the exposures generated by milling of materials not usually encountered in dust form, PNOC/R exposure limits may not be fully protective. For such monitoring, it is recommended that total dust, inhalable dust, and the smaller respirable dust fraction be measured. Exposures to potentially sensitizing materials, such as shark cartilage and ethylene diamine acid phosphate, should be maintained at levels that are as low as reasonably achievable.

7) Worker Education: Equipment maintenance and worker education are vital aspects of a good occupational health and safety program. Workers must be informed of (1) any potentially hazardous materials and (2) the nature of the potential hazard. Workers should be instructed to follow safe work practices to help protect their health and safety and that of their fellow workers. This information should be transmitted by means of a hazard communication program, which includes container labeling, MSDSs, and worker training.

8) Medical Surveillance: A medical monitoring program should be in place for the early detection and prevention of acute and chronic work-related adverse health effects:

   a) To identify those at particular risk, new employees should undergo medical history including questions regarding pre-existing respiratory symptoms and disease, including asthma. Physical examination with particular attention to the respiratory system and lung function tests, including measurement of FEV_1 and FVC, should

also be done. Under the Americans with Disabilities Act (Public Law 1-1-336 (S. 993); July 26,1990), unless these examinations reveal a disabling condition which would prevent the applicant from performing the essential functions of the job, even if "reasonable accommodations" were made, the applicant may not be refused employment. Thus, a history of pre-existing asthma would not be grounds for refusing an individual employment.

b) Follow-up medical examinations should be conducted at least annually and should include a brief respiratory symptoms questionnaire in addition to pulmonary function testing. Workers with abnormal pulmonary function or symptoms suggestive of asthma should receive a more thorough medical evaluation.

c) Individuals who develop work-related asthma should be advised of the health risks of continued exposure to the problem environment, such as worsening asthma or the development of incurable, permanent asthma. Optimally, whenever possible, they should be given the opportunity to transfer to an area of the facility which is less hazardous to them. Workers have less incentive to conceal work-related health problems or to continue working in problem areas if, after job transfer, they retain all wages and benefits associated with their previous job.

d) Employees should receive written reports of all medical surveillance tests performed by the company or by a physician to whom the company makes referral, regardless of the results of such tests.

e) New cases of occupational asthma should be reported to the Occupational Disease and Injury Services of the State Department of Health and Senior Services.

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Table 1

Results of Air Monitoring for Airborne Particulate
Allgrind Plastics, Inc.
HETA 98-0072

March 12, 1998

SAMPLE NUMBER	SAMPLE TYPE	JOB TITLE OR LOCATION	SAMPLE DURATION (min)	SAMPLE VOLUME (liters)	TOTAL AMOUNT (mg)	SAMPLING PERIOD TWA CONCENTRATION (mg/m^3)	8 HR. TWA CONCENTRATION (mg/m^3)	
							Respirable	Total
DPS-980312-01	PERSONAL - TOTAL DUST	System #1 Operator	315	687	43.88*	63.9		44.7
DPS-980312-02	PERSONAL - TOTAL DUST	System #1 Operator	136	296	2.89*	9.76		
DPS-980312-03	PERSONAL - RESPIRABLE DUST	System #1 Operator	451	780	4.27*	5.47	5.14	
DPS-980312-04	PERSONAL - TOTAL DUST	System #2 Operator	320	749	26.60*	35.5		26.4
DPS-980312-05	PERSONAL - TOTAL DUST	System #2 Operator	135	316	3.11*	9.84		
DPS-980312-06	PERSONAL - RESPIRABLE DUST	System #2 Operator	455	774	0.75	0.97	0.92	
DPS-980312-07	AREA - TOTAL DUST	~8 ft. in front of #2 mill	476	1047	0.45	0.43		0.43
DPS-980312-08	AREA - RESPIRABLE DUST	~8 ft. in front of #2 mill	477	811	0.09	0.11	0.11	
DPS-980312-09	AREA - RESPIRABLE DUST	at weigh scale of #2 mill	467	813	0.20	0.25	0.24	
DPS-980312-10	BLANK	N/A	N/A	N/A	<0.02	N/A	N/A	
DPS-980312-11	BLANK	N/A	N/A	N/A	<0.02	N/A	N/A	

***** = Sample had a total weight in excess of the recommended maximum of 2 mg. Sample also had loose particulates on the filter.

Samples collected by New Jersey Department of Health and Senior Services
Analytical Methods: NMAM (4th ed.) Method 0500 for Total Dust and Method 0600 for Respirable Dust

Table 2

Results of Air Monitoring for Airborne Particulate
Allgrind Plastics, Inc.
HETA 98-0072

April 22, 1998

SAMPLE NUMBER	SAMPLE TYPE	JOB TITLE OR LOCATION	SAMPLE DURATION (min)	SAMPLE VOLUME (liters)	TOTAL AMOUNT (mg)	SAMPLING PERIOD TWA CONCENTRATION (mg/m^3)	8 HR. TWA CONCENTRATION (mg/m^3)	
							Respirable	Total
DPS-980422-01	PERSONAL - RESPIRABLE DUST	System #1 Operator	444	755	1.61	2.13	1.97	
DPS-980422-02	PERSONAL - TOTAL DUST	System #1 Operator	444	906	12.06*	13.3		12.3
DPS-980422-03	AREA - TOTAL DUST	table between #1 feed & mill rooms	464	956	0.38	0.40		0.39
DPS-980422-04	AREA - RESPIRABLE DUST	table between #1 feed & mill rooms	463	801	0.12	0.15	0.15	
DPS-980422-05	PERSONAL - TOTAL DUST	SE-1 Operator	360	763	2.99*	3.92		2.94
DPS-980422-06	PERSONAL - RESPIRABLE DUST	SE-1 Operator	420	714	0.28	0.39	0.34	
DPS-980422-07	BLANK	N/A	N/A	N/A	<0.02	N/A	N/A	
DPS-980422-08	BLANK	N/A	N/A	N/A	<0.02	N/A	N/A	

***** = Sample had a total weight in excess of the recommended maximum of 2 mg.

Samples collected by New Jersey Department of Health and Senior Services
Analytical Methods: NMAM (4th ed.) Method 0500 for Total Dust and Method 0600 for Respirable Dust

Table 3

Endotoxin and Nitrogen Content of Powdered Shark Cartilage Samples
Allgrind Plastics, Inc.
HETA 98-0072

Material	Sample ID[†]	Dust Mass (mg)	Endotoxin[*]		Nitrogen [**]	
			EU/ml extract	EU/mg dust	Total nitrogen (µg/mg dust)	Nitrogen in material of MW > 10K daltons (µg/mg dust)
200 mesh Powdered Shark Cartilage Prepared at Allgrind Plastics	SA	565	28.28	1.25	15.1	2.0
	SB	534	24.35	1.14	14.7	13.1
	SC	541	25.83	1.19	14.4	3.2
Freshly Ground Powdered Shark Cartilage Prepared at NIOSH	2SA	613	32.50	1.33	16.6	14.6
	2SB	584	35.63	1.53	16.8	16.4
	2SC	609	29.50	1.21	17.1	15.8

[†] Values expressed are for 3 aliquots of dust taken from each source.

[*] All samples extracted in 25 ml pyrogen free water. 10 EU = 1 ng.

[**] Total nitrogen was determined using all material extracted from dust. Values for nitrogen associated with the fraction of extractable material with greater than 10,000 dalton molecular weight (MW) cutoff was determined after dialysis to remove the lower weight fraction. The larger MW nitrogen determination can be converted to total protein by multiplying times a factor of 6.25.

For Information on Other
Occupational Safety and Health Concerns

Call NIOSH at:
1–800–35–NIOSH (356–4674)
or visit the NIOSH Homepage at:
http://www.cdc.gov/niosh/homepage.html

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