NIOSH Comments to DOL

NIOSH Comments on OSHA
Cotton Dust
Advance Notice of Proposed Rulemaking (ANPR)
26 March 1982

NIOSH addresses the specific issues requested by OSHA in its 9 February 1982, Cotton Dust ANPR (47 FR 5906) as follows. It may be necessary to expand or modify this response, after the March 26, 1982 deadline established by the original ANPR because of availability of three additional secondary cotton industry reports now in preparation.

Issue 1 - HEALTH EFFECTS IN THE NON-TEXTILE INDUSTRIES

NIOSH is in the process of completing studies of five sectors of the "non-textile" or "secondary" cotton industry. The "non-textile" cotton industry is that part of the cotton industry in which the spinning of cotton yarn or the weaving of cotton cloth does not occur. NIOSH has completed studies of two of the five sectors, the cotton waste utilization industry and cotton gining. It is our understanding that preliminary drafts of these studies have been submitted to the OSHA Docket Officer. The final reports of these two studies are attached. Reports on compressing and warehousing, cottonseed oil mills and classification offices are under development and will be submitted to the Docket Officer upon their completion.

Issue 2 - NEW HEALTH DATA IN THE TEXTILE INDUSTRIES

NIOSH's comments concern the two surveys conducted by the American Textile Manufacturers Institute (ATMI), regarding the prevalence of disease and the efficacy of medical surveillance programs. According to ATMI these surveys indicate that medical surveillance has diminished the prevalence of byssinosis to .4% of the workforce. It is the NIOSH position that the survey design employed by ATMI violated many basic premises of epidemiology. NIOSH recommends to OSHA that these surveys be disregarded as credible scientific investigations of lung disease in the cotton textile industry.

Our specific comments are as follows:

Phase I Survey

a. Selection bias

The format of the survey was a questionnaire to all ATMI member companies. One hundred forty-two companies responded. It is not clear what

proportion of ATMI these 142 companies represent. The survey purports to include data obtained from 150,000 workers; in fact, it only contains responses to questionnaires sent to 142 companies, not to 150,000 individual workers.

We have no knowledge of the demographic characteristics of the 150,000 workers on whom the member companies provided information. We do not know their age distribution, sex distribution, race distribution and most importantly, the distribution of their length of employment, a very crucial factor in determining exposure. Among those companies that responded, we have no knowledge of the rate of employee turnover, nor how many workers were employed but quit in a matter of a few weeks to months and were therefore not included in medical surveillance. Although most cross-sectional studies have this problem, nearly all of them try to account for it. This study does not.

b. Ascertainment bias

After selection, there is substantial room for bias in data collection and analysis with respect to ascertaining the characteristics of the groups under study. We have no knowledge of the type and format of the individual questionnaire used by ATMI, under what conditions and by whom it was administered (self-administered, trained or untrained interviewers). Similarly, we have no knowledge of the methods used to obtain pulmonary function data. The present OSHA Cotton Dust Standard (29 CFR 1910.1043) explains in detail the acceptable tolerances for pulmonary function testing equipment, training of technicians and administration of the tests. It also clearly establishes the predicted values of Knudson, et al., as the comparison standard. We do not know if these standards were used in the ATMI study. It is a rare study in which all pulmonary function tests are acceptable, yet investigators usually mention the extent of their technical problems and the impact on the results. In this survey these issued are not addressed. Until this is clarified, the Pulmonary Function Test data are meaningless.

c. Definition of Disease State

It is well known that exposure to cotton dust causes more than one type of pulmonary reaction. First, there is the classic periodic chest tightness and shortness of breath with or without cough which begins on the first day back to work, and may continue on subsequent days. There is also a more non-specific respiratory tract irritation which results in cough and phlegm. If this continues for more than two years, it is usually defined as chronic bronchitis. Both these disease states are based only upon subjective responses received from questionnaires. In Phase I of the ATMI survey, these disease states were completely ignored. The other conditions that can occur are abnormalities in pulmonary function, either acute (defined as greater than or equal to a 10% drop in FEV_1 over a workshift) or chronic (pre-shift values abnormally low). These effects may be independent of symptoms. Again the ATMI survey completely ignores the acute pulmonary function test changes. For the chronic change, the existing Cotton Dust Standard establishes that an FEV_1 of less than 80% of predicted is indicative of chronic pulmonary impairment which warrants more frequent observation. Pulmonary function less

than 60% of predicted represents severe impairment, and may be considered disabling. However, ATMI defines the only category of disease state, which they call "byssinosis", as decrements of less than 60% of predicted in pulmonary function of individuals. Since the ATMI seems to ignore symptoms and milder pulmonary function abnormalities, it is questionable whether their member companies' surveillance programs are designed in any way to detect early indicators of disease and consequently to take appropriate ameliorative action.

d. Analysis

Most of the problems of analyses stem from inadequate controls on the cohort selection and ascertainment bias, and from the narrow definition of disease. Since age, sex, race, smoking and years of employment are not accounted for in the survey, the rate of prevalence of disease provided by ATMI is extremely crude. Since their estimation of the rate of disease is so crude, the ATMI study may have mashed certain groups among which a greater prevalence may exist. This crude prevalence is therefore meaningless and cannot be compared to earlier, scientifically valid studies.

Phase II Survey

This survey is purported to be an in-depth analysis of medical surveillance data obtained from 50,945 employees. The criticism made concerning the Phase I study also apply to the Phase II study and additional issues that require resolution.

a. Are the 50,945 workers in this survey a subset of the original 150,000 workers; if so, how and why were they selected? How were their employing companies selected to respond to the Phase II inquires?

b. At least some mention of Monday chest tightness and chronic bronchitis is made in this survey, but ATMI only states that it is aware of these diseases without elaboration.

In conclusion, unless ATMI intends to provide a more complete description of its methodologies, we must disregard the results and conclusions of their surveys, and suggest that others do the same.

Issue 3 - ACTION LEVEL

NIOSH addresses the action level as it related to medical surveillance under Issue 8.

Issue 4 - DEFINITIONS

In the present Cotton Dust Standard (29 CFR 1910.1043), OSHA has defined cotton dust as

> "dust present in the air during the handling or processing of cotton, which may contain a mixture of many substances

including ground up plant matter, fiber, bacteria, fungi, soil, pesiticides, non-cotton plant matter, and other contaminants which may have accumulated with the cotton during the growing, harvesting and subsequent processing or storage periods. Any dust present during the handling and processing of cotton through the weaving or knitting of fabrics, and dust present in other operations or manufacturing processes using new or waste cotton fibers or cotton fiber by-products from textile mills are considered cotton dust."

Bract particles and gram negative bacteria, including their endotoxins, are thought to be the components of cotton dust that cause adverse health effects. No theory of causation has been universally accepted.

As causative agents of byssinosis become elucidated, there will be need for development of new sampling methods. For example, endotoxin content of vertically elutriated cotton dust can be quantitated by the Limulus method. This type of analysis requires the services of a competent microbial laboratory. There is some preliminary indication that the analysis of total dust (collected by personal samples) for endotoxin may be an adequate index of exposure. NIOSH does not now recommend to OSHA that a microbial standard be substituted for a gravimetrically determined environmental Permissible Exposure Limit (PEL). However, if future research shows that microbial components of cotton dust are clearly responsible for adverse health effects, then OSHA may wish to consider the inclusion or substitution of a microbial PEL for the existing PEL.

Issue 5 - COMPLIANCE METHODS - ENGINEERING CONTROLS

NIOSH has no new (post 1978) information to add.

Issue 6 - TIERING

NIOSH is not commenting on this issue, since it relates to enforcement policy.

Issue 7 - COTTON DUST SAMPLING DEVICES

NIOSH has no new instrumentation or suggestions to replace the vertical elutriator. We discuss the issue of defining cotton dust in our discussion of Issue 4.

Issue 8 - MEDICAL SURVEILLANCE REQUIREMENTS

OSHA has requested comments on eight points regarding medical surveillance. NIOSH offers the following comments concerning medical surveillance.

(a). This question concerns requirements for the initial medical examination, and whether more latitude should be given to physicians in

performing these requirements. The requirements are: (1) medical history; (2) the standard questionnaire; (3) pulmonary function tests, given under certain time constraints and technical standards, using specified predicted values, and;(4) classifying persons according to Schilling's byssinosis grades. These requirements are prefaced by the statement that in the case of new employees this examination shall be provided prior to initial assignment.

A major concern, according to the ANPR of February 9, 1982, is the problem of providing pre-placement exams on all persons prior to initial assignment, especially in small companies who only hire a few employees at a time. NIOSH recommended in its 1974 Criteria Document that an examination prior to employment is essential to acquiring baseline data on the health status of new employees. In addition, NIOSH recommended that each worker be re-examined after their sixth week of employment to determine if acute ventilatory changes had taken place even after a brief exposure. It would be imprudent for NIOSH to now concur that the initial baseline examination, could be delayed for presumably weeks or months. These examinations, then, would fail to be baseline and therefore early detection of decrements in pulmonary function would not be possible.

As for the other requirements of the initial medical examination there is latitude. For instance, the content of the "medical history" is left to the physicians discretion. The mandated standardized questionnaire, according to testimony supplied in the supporting statements, is just one form of many that were provided to OSHA. This questionnaire, as are all others, was derived from the basic British Medical Research Council questionnaire which has wide acceptance. As to the technique and timing of pulmonary function testing, and the use of Knudson's prediction values, its fairly obvious that the technique must fall within certain defined tolerances and that the timing of the tests must be arranged so that they provide the optimum condition for detecting acute airway response to exposure over the workshift. Knudson's values provide the best comparison values for FEV_1 currently available. To allow other comparison values to be used would create difficulty in comparing both individual and group data.

In summary, NIOSH reiterates its conclusion that the initial examination should remain as "pre-placement", and that ample latitude be given to the examining physician, where appropriate.

(b). This issue deals with the establishment of a bronchitis and dyspnea grading system. We concur with OSHA that bronchitis, or more generally respiratory tract irritation, is a response to exposure to cotton dust independent of the classical periodic chest tightness/shortness of breath of the Schilling byssinosis classification. The World Health Organization's Study Group on Recommended Health Based Exposure Limits to Vegetable Dusts (cotton, flax, and soft hemp) recently formulated a new classification system for clinical manifestations and lung function changes in respiratory disorders. The system is based on exposure to vegetable dusts and its ability to cause byssinosis or respiratory tract irritation. This classification system is Attachment E of this submission. The new classification system

clearly defines respiratory tract irritation as a health effect, and modifies the Schilling classification of byssinosis by eliminating Grade 1/2. NIOSH proposes that this classification system be adopted by OSHA as the method of classifying subjective and objective responses to cotton dust exposure.

(c). In its 1974 Criteria Document, NIOSH, in contrast to its other recommended standards, elected not to establish an action level. At that time NIOSH concluded, based on the dose response data of Merchant et al. (1973) that the risk of byssinosis (all grades) in yarn preparation was 12.7% at 200 ug/m^3, the current standard, and 6.5% at 100 ug/m^3. There has been no recent data to suggest that the risks, as defined in the dose response curves, have lessened. Since, NIOSH still contends there is a quantifiable risk of byssinosis even at 100 ug/m^3, no action level should be set.

(d). This question raises the issue of requiring that all employees be informed of the additive adverse effects which may be caused by cigarette smoking and cotton dust exposure. There are studies that report an additional decrement in lung function among cotton dust exposed workers who smoke. However, it does not appear necessary to require that workers be informed of the perils of smoking as a part of this standard. If companies wish to include a discussion of the hazards of smoking in their health education campaign they should feel free to do so, as long as they do not misrepresent the health effects of exposure to cotton dust alone.

(e,f,g). NIOSH sees no reason to modify the sections of the standard that address maintenance of records, employer provided information, or the physicians written opinion.

(h). NIOSH sees no reason to modify the section dealing with the six-month medical follow-up of certain employees.

Finally, NIOSH reaffirms its contention that medical surveillance must be used as an adjunct to engineering controls. That engineering controls are the primary control mechanisms is an axiom of industrial hygiene universally recognized:

> "It is important to stress at the outset that periodic health examinations are no substitute for improvements in working conditions.....The medical content of examinations is not usually specific to any great degree.....The fact is sometimes overlooked that examination of a worker does nothing to eliminate the hazard. Examinations must be considered as secondary measures which are indicated when there are defects in the technical development of hygiene at the place of work. Technical improvements should be considered first, and the goal should be to make examinations unnecessary." (World Health Organization, Study on Periodic Examinations of Workers Exposure to Industrial Hazards, ICP/WKH 002, 14 June 1979).

Since Issues 9, 10 and 11 address topics outside the mandate and expertise of NIOSH, no comments are offered.

Attachment
NIOSH Submission
Docket No. H-052C
26 March 1982

CLASSIFICATON OF CLINICAL MANIFESTATIONS AND LUNG FUNCTION CHANGES IN RESPIRATORY DISORDERS FROM EXPOSURE TO VEGETABLE DUSTS CAUSING BYSSINOSIS OR RESPIRATORY TRACT IRRITATION

assembled by NIOSH 26 March 1982

SYMPTOMS

Grade 0	No symptoms

BYSSINOSIS

Grade B1	Chest tightness and/or shortness of breath on most first days of return to work.
Grade B2	Chest tightness and/or shortness of breath on the first and other days of the working week.

RESPIRATORY TRACT IRRITATION (RTI)

Grade RTI 1	Cough associated with dust exposure
Grade RTI 2	Persistent phlegm (i.e. on most days during 3 months of the years) initiated or exacerbated by dust exposure
Grade RTI 3	Persistent phlegm initiated or made worse by dust exposure either with exacerbations of chest illness or presisting for 2 years or more.

LUNG FUNCTION:

Acute Changes

No Effect	Consistently* less than 5% decline in FEV_1 or an increase in FEV_1 during the work shift.
Mild Effect	A consistent* decline of between 5-10% in FEV_1 during the work shift.
Moderate Effect	A consistent* decline of between 10-20% in FEV_1 during the work shift.
Severe Effect	A decline of 20% or more in FEV_1 during the work shift.

* A decline occurring in at least 3 consecutive tests made after any absence from dust exposure of 2 days or more

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Chronic Changes

No Effect	FEV_1* greater than or equal to 80% of predicted value+
Mild to Moderate Effect	FEV_1* - 60-79% of predicted value+
Severe Effect	FEV_1* less than 60% of predicted value+
+	Predicted values should be based on data obtained from local populations or similar ethnic and social class groups

* By pre-shift test after an absence from dust exposure of two days or more.

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony concerned the issues raised by OSHA in its 9 February 1982 Advance Notice of Proposed Rulemaking for cotton dust. NIOSH was completing studies on five sectors of the nontextile or secondary cotton industry in which the spinning of cotton yarn and the weaving of cotton cloth does not occur. Studies have been completed for the cotton waste utilization industry and cotton ginning and the final reports were submitted with this testimony. Specific comments were then made by NIOSH concerning two surveys conducted by the American Textile Manufacturers Institute regarding the prevalence of disease and the efficacy of medical surveillance programs. These comments concerned selection bias, ascertainment bias, definition of disease state, analysis, action level, engineering controls, tiering, cotton dust sampling devices, medical surveillance requirements, and the establishment of a bronchitis and dyspnea grading system. NIOSH reiterated its conclusion that, in the interests of protecting the worker, the initial examination should remain as a preplacement function and that ample latitude be given to the examining physician, where appropriate.

17. Document Analysis a. Descriptors

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