PLAINTIFF'S EXHIBIT
UC-4477

DRAFT

Asbestos

To: Dr. A. L. Baye
Linde Div.
8th Floor

TESTIMONY REGARDING

16 CFR Parts 1304 and 1305

RESPIRABLE FREE-FORM ASBESTOS

Proposal to Ban Certain Patching

Compounds and Artificial Emberizing

Materials (Embers and Ash)

As Published in the FEDERAL REGISTER,
Vol. 42, No. 146 - Friday, July 29, 1977

Presented by Harrison B. Rhodes
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Niagara Falls, New York 14302
August 15, 1977

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My name is Harrison B. Rhodes and I am speaking on behalf of the Union Carbide Corporation where I hold the position of Technology Manager in the "Calidria" Asbestos Department. My education is in the field of Chemical Engineering where I hold the degree of Dr. of Science from Columbia University. For the past four years my assignment has been in the area of asbestos health and regulatory matters and has also included research on monitoring techniques. I am currently serving the Asbestos Information Association/North America as Chairman of the Standards and Technical Committee, Cochairman of the Ad Hoc Committee on Construction, and Chairman of the Subcommittee on Monitoring Procedures.

Union Carbide Corporation has been actively engaged, since 1962, in the mining and milling of asbestos ore at facilities in central California. The asbestos fiber produced is marketed throughout the United States and in many foreign countries. One of the principal applications in this country has been in tape-joint compounds. We do not ourselves manufacture such compounds, however, nor do we manufacture any other asbestos-containing finished products.

As the Commissioners are well aware, there has been a tremendous flood of "paper" generated in relation to the asbestos regulatory matters under consideration here and we believe that several critical issues have been lost in the flood. We would like to take the opportunity today to focus on these issues, discuss the regulatory principles involved, and suggest an approach which we believe is consistent with the facts available. Some additional directly relevant exposure data will also be presented.

It should be emphasized that this discussion will deal directly with, and be presented, in terms of tape-joint compounds. Spackling compounds are similar in composition and use, but are applied in so much smaller amounts that the potential for significant exposure is virtually non-existent.

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Emberizing kits are outside of our field of expertise and will not be considered.

By way of background, gypsum wallboard was developed around 1880-1900. It did not come into wide usage until World War II where the need for houses and other buildings made this quicker, less complex construction method very popular. Usage has grown substantially since that time and drywall construction is now used in a majority of residual RESIDENTIAL construction and in a wide variety of commercial and public buildings. Wallboard production has increased from two billion square feet in 1946 to a peak of 15 billion square feet in the boom year of 1973 and 13 billion square feet in 1976.

The joining of the wallboard went through an evolution that included perforated metal tape, cloth mesh, perforated paper and the present paper (Spark perforated & unperforat) were used to bridge the crack. Initially, ordinary plaster was used to embed and cover the tape, but in the mid 40's specially formulated dry mixtures with casein as the binder were introduced. These mixtures typically contained 10-15% asbestos. We have been told that the plaster of that time also contained asbestos.

Ready-mix, i.e., wet compounds were introduced in the mid 50's and were in broad general use by 1960. The asbestos content of muds in general dropped during the 70's to approximately the range of 2-7%. Tape-joint compounds containing asbestos have thus been in widespread use of 30-35 years. Over the first 15 years of this period the main material used was provided dry and contained relative high (10-15%) levels of asbestos.

The Commission's consultant, A. T. Kearney, Inc., has estimated that today's annual value of shipments of patching compounds is 80 million dollars. At an average price of $4.50 per 62.5 lb. can this is equivalent to about 560,000 tons of product contained in 17.8 million cans. The formulations we

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have seen cost about 20-30¢ per can in raw material costs to replace asbestos so that the added burden, just to cover raw materials costs is about 4.5 million dollars annually. This cost, plus any percentage markups used, would be added to the cost of the structure and would carry the normal financing charges over the life of the indebtedness. It should also be noted that at a 3% loading the 560,000 tons of product would contain about 17,000 tons of asbestos with a product value around 1.7 million dollars. We believe that the total of 6.2 million dollars annually presents a reasonably reliable minimum estimate of the direct economic effects of the replacement of asbestos in tape-joint compounds being forced by the Consumer Product Safety Commission and other governmental agencies. The added effect of poorer performance has not been considered.

In the assessment of the risk that needs to be related to this cost burden, it is important to have a reliable estimate of the level of consumer exposure. All of the available information on exposure has been assembled and is discussed in detail in an Appendix to this presentation which will be submitted prior to the August 29, 1977, discussion. Only the key results will be summarized here.

The data presented are contained in five reports:

1. The tests conducted by Rohl et al[1] at one location in New York, NY. This is the data cited by the petitioners.
2. A survey of a variety of sanding conditions made by Rhodes and Ingalls[2] and cited extensively by the Asbestos Information Association/North America in their response to the petition.

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1. Rohl et al, Science, Volume 189, August 15, 1975, p. 552.
2. G.D.C.I. Drywall, January/February 1976.

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3. Data from State and Federal OSHA compliance inspections compiled by Equitable Environmental Health Incorporated as part of a study of asbestos exposure in the construction industry.
4. A report submitted to the CPSC by Union Carbide Corporation on July 14, 1977, covering consumer exposure during a typical spackling and a moderate size drywall installation operation.
5. A study by Union Carbide which has just been finished on another consumer installation of a large room including the ceiling.

The results of this survey are summarized in the two figures you are now receiving. Figure 1 shows along the vertical axis, the airborne asbestos concentration, in fibers per cubic centimeter longer than 5 micrometers, that occurred in the breathing zone of the operator during the sanding operation. Usually a number of samples were collected at each location, the dark bar shows the range of concentrations found with the arithmetic average of all samples indicated by the arrow. The "P" and "H" along the bottom show whether the sanding was by hand or by pole and the numbers show how many samples made up the average.

The data on the left are those of Rohl et al that were cited in support of the petion. These were obtained in one test in New York City and appear to consist of a number of very short, i.e., 1 to 1.5 minute samples. Short samples typically fluctuate widely so it is probably most appropriate to look at the mean values of 10 fibers/cc for pole sanding and five fibers/cc for hand sanding. It should be noted that consumers basically sand by hand.

The next group of data were obtained by Union Carbide in conjunction with the Gypsum Drywall Contractors International. These samples were collected at a variety of commercial sites selected as representative by GDCI and operating under everyday job conditions. The range here is from 0.2 to about 3 fibers/cc.

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When the wide differences between these data and those of Rohl became apparent, six of the filters were checked "blind" by two other laboratories. The agreement was good. Details were included in the AIA/NA presentation to the Commission and are also shown in the Appendix.

The last group of commercial data was assembled by Equitable Environmental Health, Incorporated, and consists of two short tests conducted by EEH and results from OSHA compliance inspections at four job sites. The EEH tests were very short and very little asbestos was generated. The OSHA data cover the range of about 0.2 to 3 and look very much like the Union Carbide results.

The most important data for the present consideration are the two consumer tests shown on the right of the figure. One result is for the case of extensive spackling and the removal and replacement of three 4' x 8' drywall panels and was reported in detail to the Commission on July 14, 1977. Five lbs. of dry-mix compound were used. Since that time five of the filters have been checked by a second laboratory and the average differed by less than 20%. As might be expected, the range here for the much smaller scale job was quite low at 0.3 - 0.5 fibers/cc >5μ.

The second test was run on a larger scale with 19 panels of drywall installed in a 24' x 12' recreation room to cover three walls and the ceiling. Approximately 80 lbs of ready-mix compound containing 1.75% asbestos on a wet basis and 2.6% on a dry basis was used. Two people hand sanded twice here and the breathing zone concentrations ranged from 0.3 to 0.5 fibers/cc >5μ.

The other two operations of interest, wet-out of dry materials and cleanup after sanding, are shown in Figure 2. Here, in order to get the Rohl et al data on the graph it was necessary to run the scale from zero to sixty instead of zero to twenty as in the previous figure. The presentation follows the same format, otherwise.

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The wet-out of dry materials is shown on the left-hand part of the figure. Commercial material is usually packaged in a 25 lb. bag and one or several such bags were dumped into water in the operations shown. The Rohl data gave a mean of 47 fibers/cc whereas OSHA inspections at five locations had a range of 2.7 to 5.4 fibers/cc >5μ and a mean of about 4 fibers/cc. The only consumer mix of 5 lbs. gave 0.3 fibers/cc >5μ.

The sweeping and cleanup data are given in the right-hand side of the figure. The Rohl data are again very high whereas OSHA shows a range of about 0.5 to 2.

Interestingly enough, the consumer results, although still quite low, showed the highest levels during cleanup. The small job was swept up with a pan and brush with a level of 0.3 fibers/cc and a level of 0.5 fibers/cc occurred for a short period while the clothes were being shaken prior to washing. For the larger scale test the range was 0.6 to 1.3 during sweeping and during vacuum cleaning.

It is very important to understand that all of the concentrations shown occurred during the active pursuit of the particular operation, i.e., sanding, wet-out, or cleanup. These operations generally take place for a moderate portion of the day with concentrations at much lower values for the rest of the 8 hour period. Eight-hour time-weighted average exposures for the commercial sanding operations studied by Rhodes and Ingalls shown in Figure 1 ranged from 0.1 to 0.9 fibers/cc >5μ. For the smaller scale consumer installation the highest values obtained were 0.3 fibers/cc for the first day, which was mainly from rip out of the old wallboard, 0.02 fibers/cc for the second and 0.01 fibers/cc for the third. In the full room installation the results for each combined sanding and cleanup operation were:

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First day -

Operator A -

Operator B -

Second day -

Operator A -

Operator B -

In both tests, samples collected before and after the installation give the same values so no lingering asbestos exposure had been generated.

One of your staff members, Dr. Stephen Bayard, has developed a model[1] to estimate the risk of respiratory cancer from low level exposure to asbestos from taping compounds. This model is patterned on that described in paper by Enterline and Henderson[2] except that Dr. Bayard has made an assumption that the effect of dose is cumulative. This builds a geometric increase in risk into the model. We question whether there is any basis for this assumption, but do not feel that this is an appropriate place to debate the issue. It is of more interest to use this model, which is heavily loaded to predict high risk with the highest exposure just described for consumer use.

Following Dr. Bayard's directions in page 3, Part C, of the reference cited for the highest time-weighted average of 0.3 fibers/cc for two days found for the consumer applications we obtain an annual exposure rate of 0.003 fibers/cc per day, a latent period to tumer of 682 years, 0.00X deaths of asbestos induced cancer, and a relative risk of . This is probably on the high side due to assumptions used in building the model but since an exposure of 0.003 fibers/cc is indistinguishable from background, it is not unreasonable. We question whether this is the "unreasonable risk" referred to in the statute.

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1. Memorandum to Dan Clay dated June 3, 1977.
2. Presented at Pinehurst, NC, March 12, 1976.

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Let us now relate this risk to the proposed ban of consumer patching compounds containing respirable, free-form asbestos under Sections 8 and 9 of Consumer Product Safety Act. To quote Section 8:

"Sec. 8. Whenever the Commission finds that--

(1) a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and

(2) no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product,

the Commission may propose and, in accordance with section 9, promulgate a rule declaring such product a banned hazardous product." (Emphasis added.)

And from Section 9, Paragraph 2 (c):

(2) The Commission shall not promulgate a consumer product safety rule unless it finds (and includes such finding in the rule)--

(A) that the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product;

(B) that the promulgation of the rule is in the public interest; and

(C) in the case of a rule declaring the product a banned hazardous product, that no feasible consumer product safety standard under this Act would acequately protect the public from the unreasonable risk of injury associated with such product.". (Emphasis added.)

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Note particularly the repeated use of the words "unreasonable risk" and the requirement to eliminate or reduce unreasonable risk, not to make this risk to zero. The Act makes it quite clear that the intent is not the total elimination of all risk but of "unreasonable risk" and it delegates to the Commission the complex and soul-searching problem of deciding what is "reasonable".

The comments of your own staff on the strength of the evidence used to support the ban is well summarized by three short quotations from the record:

> "The petitioners believe that high quantities of asbestos fibers remain in the air after these products are sanded and the fibers substantially increase the risk of mesothelioma and lung cancer." (1)

> "The petitioners have addressed problems which arise from being exposed to asbestos fibers occupationally and environmentally. However, they have not cited any concrete evidence of the hazard which is tied directly to the products for which they seek a ban. It merely cited the fact that these products do contain asbestos fibers and they have cited the fact that asbestos fibers in other situations have been linked to lung disease. We question whether the evidence presented in the petition is sufficient to show that these substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use." (Emphasis added.)(2)

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(1) CFR, Vol. 42, No. 146 - Friday, July 29, 1977 p. 38790.

(2) Letter of July 11, 1976, from Charles M. Jacobson, BCMI to Francine Shacter, TAD, OSCA.

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"The instances of single or short-term exposure to asbestos cited in the petition can be taken as evidence of a possible (but not necessarily probable) cause-effect relationship. However, by themselves, they would not stand up to statistical scrutiny in predicting a correlation between brief exposure to asbestos and the later development of cancer caused by such exposure." (3) (Emphasis added.)

Substantial evidence has been presented here that the commercial use data upon which the petitioner's based their allegations is substantially higher than that of all other investigators (including OSHA compliance inspections). It has also been shown that consumer exposures are low, of short duration, and when averaged over a year or more are not distinguishable from ambient background. We know of no evidence that such casual, low exposure represents any hazard so that the question becomes one of a banning action based on the existence of a possible, but not proven risk, which if it exists at all differs only slightly from zero.

You are probably aware, that this question of the regulation of carcinogens is a major issue today before virtually all of the governmental regulatory agencies. The FDA saccharin ban has received wide publicity and OSHA is deeply involved with a proposal for a generic regulation approach to carcinogens and hearings on benzene are now in progress. All of this activity does not help to find answers to our immediate problem, but we are at least in good company.

The problem we face originates in the so-called "one-hit" theory of carcinogenisis. In simplest outline, this theory holds that:

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(3) Briefing Package, February 2, 1977, presented to the Commission by Fracine Shacter.

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1. A single molecule of a carcinogen is capable of causing cancer in a particularly susceptible person.
2. If enough people are exposed, the susceptible person (or small number of such persons) will contract cancer.
3. It follows, therefore, that there is no absolutely safe or zero risk level for a carcinogen and such a material should, depending on the statutory authority of agency involved, be banned, severely restricted, replaced, controlled to the limits of detection, etc.

It is useful to examine this theory in the light of where there is general agreement and where responsible opinions diverge. We believe that virtually all medical authorities would agree:

1. That there is a wide range of dosages for a carcinogen where a dose-response relationship exists. The larger the dose, the greater percentage of these exposed contract cancer and vice versa.
2. In exposed populations, even at substantial exposure levels, large proportions of those exposed do not contract cancer.
3. As the dosage goes down the average time to the appearance of a tumor increases. This principle was illustrated by the extrapolation formula of Enterline and the Bayard modification discussed previously.

The medical disagreement occurs over what happens as the dosage is decreased to very low levels. There is one school of thought, and this is embraced by most of the regulatory agencies, that no completely safe level exists. There are other responsible authorities who contend that a dosage level is

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reached where the body's defense mechanisms can effectively combat the altered cells and a cancerous growth does not occur. Supporters of this position cite the low level presence of certain metals and hormones that are essential to the human body in trace amounts but at higher levels are carcinogens.

Unfortunately, there is no way to demonstrate the correctness of either view since there is a background level of cancer in both man and experimental animal. As the dosage and the corresponding number of cancers decreases one point of view is that the occasional cancer from the specific agent still occurs but cannot be distinguished from the background noise while the other is that the added cases do not occur. These views can be partially resolved with the model of Enterline discussed previously, i.e., a very low exposure may cause a cancer but the time to tumeris 150 years for example. With an expected life span of 70 years this, for all practical purposes is a safe threshold exposure, at least until life expectancy approaches 150 years. Since there is no provable scientific answer to this risk question, we are really left with a socio-politcal rather than a scientific decision to consider.

The fundamental question, then, is whether a total absence of risk approach to regulation is appropriate or more particularly will be acceptable to society. In our lives we undergo a succession of risks, some knowingly and some unknowingly. The American people have always indicated a willingness to take risks as evidenced by such things as the widespread use of the automobile, smoking, alcohol, improper diet, and even the home as it is today. We believe that the zero risk concept, when it begins to impact on jobs and the way of life of a substantial number of people will not be acceptable and will have to be modified to balance risks against benefits in a realistic fashion. This sort of balance rather than regulation by cliche, "its a carcinogen so ban it", should be applied here. The benefits from the continued use of asbestos in

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tape-joint compounds is substantial and the risk is either zero or so small it cannot be distinguished from zero.

This finishes the risk-benefit discussion and I would like to conclude this presentation by pointing out certain practical aspects of enforcement in the Federal Register. These questions were discussed at great length, and generally were not solved, at the recent meeting in Gaithersburg, MD, conducted by the National Bureau of Standards. Since several members of your staff were present at this meeting, they will only be indicated briefly.

Since the promulgation of the OSHA asbestos regulations in 1972 there has been a continuing debate on what is asbestos and what is an asbestos fiber. Asbestos, when narrowly defined, in a way that will satisfy the most precise minerologists is ubiquitous in the atmosphere although generally it occurs at very low, but not zero, concentrations. When the definition is broadened to include all amphibole chips which are longer than 5 microns and have a length to diameter ratio greater than 3, you approach a condition aptly described by Dr. Malcom Ross of the U.S. Geological Survey at the NBS meeting just mentioned, of "shutting down the face of the earth". Particles of this type are everywhere and would contaminate any product containing minerals.

The EPA faced this problem in 1973 in writing emission standards for the spraying of asbestos-containing products and decided to treat it by setting a 1% by weight maximum limit. Their reasoning was as follows:

> "The intent of the 1-percent limit is to ban the use of materials which contain significant quantities of asbestos, but to allow the use of materials which would: (1) Contain trace amounts of asbestos which occur in numerous natural substances, and (2) include very small quantities of asbestos (less than 1 percent) added to enhance the material's effectiveness.[1]

1. CFR, Volume 38, No. 66 - Friday, April 6, 1977, p. 8821.

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In order for any action by the Commission to be workable and enforceable it is absolutely essential that you provide a definition of "asbestos" which states exactly what mineral species and what form of these species are included and specify what particle dimensions constitute an asbestos "fiber". The present definition in the proposal could be applied to the rock that covers much of the surface of the earth. In addition, an analytical procedure and the levels of "impurities" that are acceptable, as measured by this procedure, must be specified. Without the practical definitions the ban is virtually universal and completely unworkable.

To conclude this discussion, I would like to summarize the Union Carbide position and expand on the approach presented in my letter of July 14, 1977, which we believe is a reasonable alternative to the ban proposed by the Commission.

1. The products under consideration have been in widespread use for about 35 years and there is no evidence that any consumer has ever been harmed by them. No "unreasonable risk" to the consumer has been demonstrated by the petitioners or by the staff.
2. Consumer exposure data have been presented which show that the exposures are both low and brief and when averaged over a year are not distinguishable from the general background. The risk from such exposure, if indeed any risk does exist, is extremely small and is based on the extrapolation of an unproven and unproveable theory.
3. We question whether it is appropriate and whether the Act gives the Commission the authority to ban a product on the basis of a hypothetical or theoretical risk on the basis of an absolute zero risk requirement.

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4. We do not agree that a reasonable product safety standard cannot be promulgated to protect the public adequately from any unreasonable risk and recommend the following approach:

   a. Limit the amount of asbestos that can be used in spackling and taping compounds to two percent by weight in the dry formulation. This is sufficient to gain the benefits of the use of asbestos and serves to limit the potential for exposure. It differs from the 1% of total formulation suggested previously in that it more closely defines the content in the final product to be sanded. It is also at a level where analysis is more reasonable.

   b. Require a warning label including proper work procedures on all compounds under the jurisdiction of the commission whether packaged for direct consumer or commercial use in consumer contact. This turns to good advantage the widespread public awareness of the possible potential hazards of asbestos to encourage that the product be treated according to directions and not abused. It also gives the user a choice.

Thank you very much for this opportunity to speak to the Commission. I will be glad to answer any questions you may have or to provide any additional information we have available.

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AIRBORNE ASBESTOS CONCENTRATIONS
IN OPERATOR BREATHING ZONE
DURING SANDING OF TAPE-JOINT COMPOUND

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AIRBORNE ASBESTOS CONCENTRATIONS

IN OPERATOR BREATHING ZONE

DURING WET-OUT OF DRY MATERIALS

AND

CLEANUP AFTER SANDING

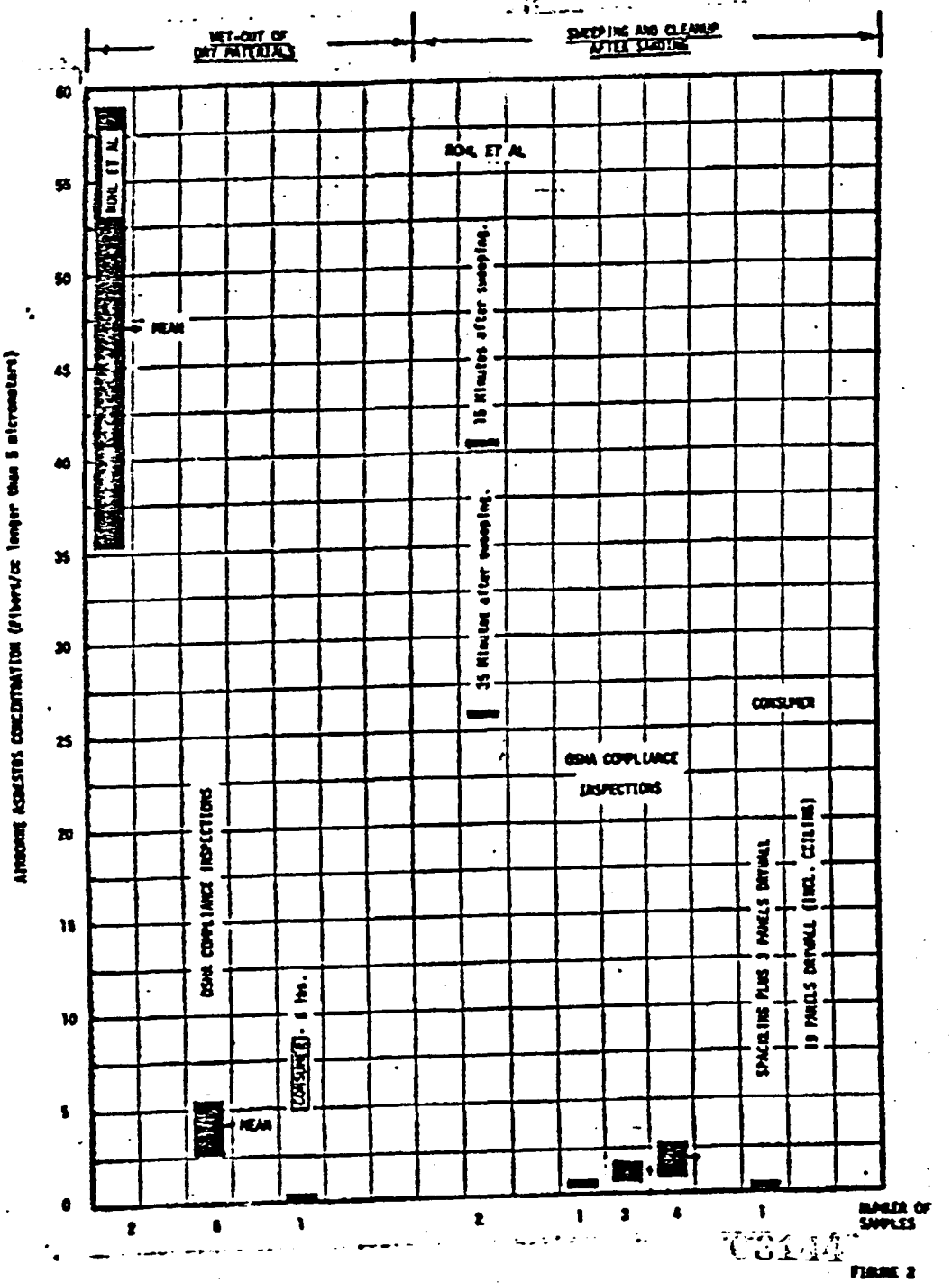


FIGURE 2

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