FROM

JUDITH A. LYTLE

PITTSBURGH OFFICE - 12

TO

MR. M. J. VAUDREUIL

PITTSBURGH OFFICE - 6

1980 SEPTEMBER 03

RE: COMMENTS TO EPA RE: ASBESTOS USES

Pursuant to your request, attached is a copy of the comments submitted by Alcoa on TSCA Section 8(d) proposed regulations. This is illustrative of the format that we have used previously. I understand that you will forward to me a copy of your draft comments for review prior to submitting them to the Agency.

If you have any questions regarding this, please do not hesitate to call.

J. A. LYTLE

JAL:pd

Attachment

H & S
Industrial Hygiene

BDD	SEP 4 1980	MLF
EER		RWF
TBB		CD
RMJ		DB
BLS		LMN
PHS		EDS
MJV.		

PLAINTIFF'S
EXHIBIT
AL-1656

ALCOA

LEGAL DEPARTMEN

FORM 3998 REV 6 75

ALUMINUM COMPANY OF AMERICA

ALCOA BUILDING · PITTSBURGH, PENNSYLVANIA 15219

LEGAL DEPARTMENT

ALCOA

1980 February 28

Document Control Officer
OTS-084003
Office of Toxic Substances (TS-793)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Re: Health and Safety Data Reporting: Submission of Lists and copies of Health and Safety Studies

Gentlemen:

Aluminum Company of America ("Alcoa") hereby files its comments on the proposed rule for Health and Safety Data Reporting under section 8(d) of the Toxic Substances Control Act, pursuant to notice contained at 44 Fed. Reg. 77470, 1979 December 31.

Sincerely,

Judith A. Lytle

Judith A. Lytle
Attorney

JAL:pd

Received
DCO
Lois B. Riley
2-29-80

79-3300-40A-2

COMMENTS

OF

ALUMINUM COMPANY OF AMERICA

Aluminum Company of America ("Alcoa") hereby files its comments on the proposed rule on "Health and Safety Data Reporting: Submission of Lists and Copies of Health and Safety Studies" pursuant to notice contained at 44 Fed. Reg. 77470, 1979 December 31.

I. General Requirements of the Rule

A. Scope of the Proposed Rule

Through the proposed rule, EPA intends to gain access to unpublished studies on the numerous chemical substances and mixtures currently listed at 40 CFR 716.13, as well as an unknown number of additional substances and mixtures to be added to the list at EPA's discretion. Obviously, the vast number of substances subject to the proposed regulation, some of which are particularly prevalent in the environment, will mean that the amount of information generated by the rule will be substantial. Alcoa believes that each substance recommended by the Interagency Testing Committee for priority consideration, or selected by EPA for evaluation of health and environmental effects, should be individually considered by

EPA. In other words, only if EPA's efforts to accumulate adequate data concerning effects from published studies and/or studies reported to the Agency pursuant to other requirements of the Act, do not result in satisfactory quantity or quality of data for carrying out its regulatory function under TSCA, would the Agency proceed to require disclosure of unpublished data on the particular chemical under consideration.

It is widely known that there is a substantial amount of published data on many of the substances listed at 40 CFR 716.13, such as aryl phosphates, asbestos, benzene, methylene chloride, isophorone, methyl ethyl ketone, toluene, and xylene. The Act specifies that "the Administrator shall carry out this Act in a reasonable and prudent manner, and ... shall consider the environmental, economic and social impact of any action the Administrator takes or proposes to take under this Act." 15 U.S.C. §2601(c). Alcoa believes that it would be reasonable and prudent for EPA first to assess published and available studies on a particular chemical under regulatory consideration; to Alcoa's knowledge EPA has not systematically organized or reviewed such material. If after review, EPA determines that the available information is inadequate, then the production of unpublished studies could be mandated.

Alcoa believes that a blanket request for unpublished studies, no matter what the available quantity or quality of published studies on a given substance or mixture, will lead inevitably

to the collection, at substantial cost, of duplicative information which in fact contributes nothing additional to the appreciation of the human or environmental effects of such substances. In many cases, adequate data should be available to the Agency by use of published studies.

Alcoa further believes that EPA should establish criteria for adding substances to the list at 40 CFR 716.13. Alcoa believes that the list should be limited to chemical substances, categories of substances, or mixtures which the Interagency Testing Committee recommends for priority consideration by EPA. That would help to ensure that the quantity of information submitted to EPA would be manageable, and that those substances which pose threats requiring immediate action by EPA will be focused upon.

B. Definitions

One of Alcoa's major concerns with the proposed regulations is that several key terms are not clearly defined.

"Health and Safety Study" is defined as "any study of an effect of a chemical substance or mixture on health or the environment, or on both, including underlying data and epidemiological studies, studies of occupational or environmental exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other environmental studies of a chemical

substance or mixture, and any test performed under TSCA." 40 CFR §716.12(b);(c). Examples listed include:

> "(iv) Studies measuring or estimating concentrations of a particular chemical(s) any where in the environment, including the workplace."
>
> "(v) Studies measuring or estimating human or environmental exposure to a particular chemical(s) anywhere in the environment, including the workplace."
>
> "(vi) Industrial hygiene surveys."

The definition contained in the proposed regulations and the examples given are not intended to expand upon the definition of "health and safety study" contained in the Act:

> "The term 'health and safety study' means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies; studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act." 15 U.S.C. § 2602 (6).

Alcoa believes that to be reportable under Section 8(d) of the Act, a study must be one that examines <u>effects</u> of a chemical substance or mixture on health or the environment. Thus, while monitoring results might form part of a study, they are not <u>studies of effects</u> themselves, and reporting them is not required under section 8(d) of the Act.

Although 40 CFR 716.15 (a)(2) indicates that "medical or health records and daily monitoring records supporting exposure monitoring or epidemiological studies do not have to be submitted unless requested," because they are deemed to be "underlying data," the fact that monitoring "studies" and "industrial

hygiene surveys" are included in examples of health and safety studies at 40 CFR 716.12(c)(1), casts considerable doubt on how EPA will view them, as reportable or not under the proposed regulations. Alcoa believes that monitoring data, unless thoroughly analyzed and made part of a formal study, would not be useful to the Agency; it would not be indicative of effects on health or environment, and Alcoa understands that information on such effects is what would be of value to EPA.

Alcoa believes that only those studies culminating in chemical and scientific findings on exposure effects and/or toxicity can be of assistance to the Agency in its evaluation of potential harm posed by a particular substance or mixture. To exclude concentration and monitoring surveys and other incomplete or informal studies, whose scientific reliability would not merit their production, Alcoa recommends that health and safety study be defined more clearly as:

> "a formal investigation utilizing defined scientific methodologies and yielding conclusions on the effects of a chemical substance or mixture on health or the environment or both. Such investigation must include monitoring a control area or group, recording of exposure levels, and analysis of epidemiological results of exposure.

Alcoa believes that by defining Health and Safety studies in such a way, by defining "Copies of Health and Safety Studies" as "final reports from the principal investigator(s)," and by retaining 40 CFR 716.15(a)(2), which excludes from the copy requirement underlying data, EPA will be able to acquire valuable information of scientific integrity which truly

examines the effects of chemical substances and mixtures on health and the environment. Because 40 CFR 716.13(c)(1) (iv), (v) and (vi) are not health and safety studies in themselves, but may be parts of a health and safety study and ultimately reportable to EPA as underlying data under 40 CFR 716.15(a)(2), they should be excluded from 40 CFR 716.13.

"Manufacture for commercial purposes" is defined by the proposed regulations to include both byproducts that are separated from a chemical substance or mixture and impurities that remain in the substance or mixture, whether or not they have any commercial value in themselves.

Alcoa does not believe that the proposed regulations' copying and listing requirements should extend to byproducts and impurities. In most cases, we believe that the requirement to submit studies on these would provide little, if any, valuable information to EPA beyond that already supplied by studies of manufacturers, processors and distributors. In cases in which impurities and byproducts are known to be of sufficient toxicity in relation to health and safety considerations, studies should be obtained on an individual basis through separate rulemaking.

C. Copies of Health and Safety Studies

The proposed rule would first require all manufacturers, processors and distributors of any chemical substances or

mixtures (even if none is listed at 40 CFR 716.13) to submit copies on chemical substances and mixtures listed at 40 CFR 716.13. Thus, in order to be included within this requirement, the manufacturer, processor or distributor need not be manufacturing, processing, or distributing the particular chemical that is the subject of the study, nor need he ever have proposed to do so. Alcoa believes that this is extremely overreaching, in that, by definition, the requirement covers every conceivable manufacturing, processing and distributing entity within the Agency's jurisdiction, and it requires each of them to report on all listed chemicals, no matter how remote the entity's interest or involvement with the particular substance or mixture. Particularly when very prevalent substances or mixtures are involved, this requirement could result in an avalanche of repetitive information.

Alcoa believes that only those closely involved with a particular substance, i.e., those who are presently manufacturing, processing or distributing a substance or mixture, or who have done so in the past, or who have proposed to do so, should bear the initial burden of submitting copies of final studies. These will obviously be the parties with the greatest interest in developing data, and thus the ones most likely to possess it. To place a burden of submitting copies of studies on virtually every manufacturer, processor and distributor in the United States as to all substances and mixtures on the extensive proposed list, which will be supplemented from time

to time, will necessarily result in duplicative, and undoubtedly in some instances meaningless, information which cannot be efficiently digested by the Agency. Therefore, the Agency should look to those with the greatest interest and stake in development of data on a particular substance or mixture; it is anticipated that both quantity and quality of reported data would thereby be assured.

As an alternative to the proposed requirement and to Alcoa's suggestion, EPA has indicated that another option might be to require any person who manufactured, processed, or distributed a listed chemical(s) to submit copies of studies it possesses on any listed chemical. Alcoa feels that this too would be more far-reaching than is advisable, if it is an efficient and reliable reporting system that is desired. Almost any United States manufacturer, processor or distributor would find himself subject to such a provision, and Alcoa's arguments would parallel those it raised above against the proposed rule's coverage. Further, Alcoa can discern no correlation between the fact that one does or does not manufacture, process or distribute at least one of the listed chemical substances or mixtures, and his access to reliable studies on all other listed chemicals.

Alcoa recommends that the requirement for submission of copies of studies should be limited first to past and present manufacturers, processors, or distributors of the listed substance which is the study's subject, and second, to those identified

as possessing a study listed by someone else in accordance with 40 CFR 716.16 of the rule. Alcoa agrees that the latter should be requested by letter by EPA, only if the Agency is not otherwise in possession of the particular study.

Alcoa agrees with EPA that underlying data, such as medical or health records and daily monitoring records supporting exposure monitoring or epidemiological studies, should not be routinely required of one supplying a copy of a health and safety study. Alcoa believes that EPA should request medical or health records, which are sensitive and confidential material, only if the report supplied to it cannot be reliably assessed without such additional data. Further, it is Alcoa's position that a compilation of such underlying data would satisfy EPA's needs. If EPA determines, however, that individual medical or health records underlying a particular study are essential to EPA's assessment of that study, then any notations identifying the subject of the medical or health report being submitted, should be removed at the submitter's discretion.

D. Lists of Health and Safety Studies

Alcoa agrees that only those currently engaged in the manufacture, process or distribution of a listed chemical substance should be required to list studies pursuant to proposed 40 CFR 716.16. However, Alcoa does not agree with EPA's proposal that ongoing health and safety studies, conducted by or for the company, should be listed. Alcoa believes that the value of

reporting on an ongoing study would be extremely tenuous; until there are definitive results, such a study has no scientific integrity.

Further, Alcoa understands that as proposed, "health and safety study" would cover such things as monitoring of chemical concentrations in the workplace. In the case of asbestos, for example, Occupational Safety and Health standards require monitoring if employees are exposed. Alcoa understands that according to the proposed rule, a company would be required to report such routine monitoring. Alcoa can foresee no benefit to listing such "studies"; indeed Alcoa doubts that such monitoring data are studies at all for Section 8(d) purposes, and asserts that unless ongoing studies are ultimately to address <u>effects</u> of environmental or employee exposures, listing is meaningless and should not be required. It is only when concentrations are in some way correlated to toxicity effects that the Agency can attempt to assess meaningfully the degree of potential danger presented to the environment or the employee by the chemical, and it is that assessment which the rule proposes to aid.

E. Reporting Time

Alcoa does not believe that the extensive file searches which will be required upon promulgation of the proposed rule can be done within the proposed sixty (60) day time period. Like many

other multi-site corporations, Alcoa's efforts at accessing data on all listed chemical substances and mixtures at all of its locations will require extensive time and effort. Alcoa recommends that a period of 180 days be permitted for the initial reporting interval, with a thirty day extension period available on request, if approved by the Agency.

II. Impact Analysis

Alcoa takes particular exception to the Administrator's note accompanying the proposal stating that the Environmental Protection Agency has determined that the proposed regulations do not contain a "major proposal," such that Regulatory Analysis according to Executive Order No. 12044 is not necessary. Order 12044 specifies that the determination of significance may depend on whether the proposal will result in major economic consequences for the general economy, or for particular industries or particular geographical regions or governmental levels.

It is Alcoa's contention that the proposed rule will necessitate the expenditure of considerable time and money for compliance by the chemical industry in particular, and by all industries that rely heavily upon chemical substances in production.

The Environmental Protection Agency estimates a $411,000 cost of compliance, with a ± 30% margin of error. Estimated cost

will therefore fall between $288,000 and $534,000. For several reasons, Alcoa believes that this is far too modest an assessment.

First, it is unclear from the Federal Register notice whether EPA considered all of industry's projected compliance costs, or simply those of the chemical industry. ("Spread over the entire chemical industry, such a cost is extremely minor." 44 Fed. Reg. at 77474). It appears that the compliance costs of those involved in industry other than the chemical industry and of all persons reached under 40 CFR 716.17 ("Persons in Possession of Listed Studies") have been overlooked by EPA. In fact, the "Reports Impact Analysis" of the proposed rule, prepared by EPA, indicates that such costs were overlooked.

In its cost analysis, EPA assumed that four hours would be required to search each plant site or other location, and that each firm subject to the regulations would average 1.5 establishments per firm. Using the two assumptions, EPA thus estimated that it would take an average of six hours for each firm to complete its file search.

These assumptions and calculations, however, were based upon the chemical industry alone. As stated above, Alcoa believes that the mandates of the proposed regulations reach far beyond the chemical industry, and in fact touch virtually every manufacturing, processing and distributing entity in the United

States. Even though searches by many of these entities may not produce submittable studies, the time consumed in such searches must still be considered in the Agency's economic analysis.

Further, Alcoa strongly disagrees with EPA's estimate that 2.6 firms will respond on each chemical listed, based upon the original Section 8(d) rule. The original rule covered thirty-one chemicals, while the newly proposed list contains 356 additional ones, and is subject to discretionary expansion by EPA. Since a significant number of the chemicals on the proposed list are extremely prevalent, (e.g., aryl phosphates, asbestos, benzene, methylene chloride, isophorone, methyl ethyl ketone, toluene, and xylene) and the scope of the proposed regulations is so extensive, Alcoa believes that hundreds of companies would be required to submit studies on many of the listed substances. Further, Alcoa believes that the cost of searches would be more realistically estimated as $40 per hour, rather than $20 per hour, as in the "Reports Impact Analysis."

EPA also projects that approximately 926 firms will respond to the requirement of submitting lists of ongoing studies and studies in the possession of others. Again, Alcoa believes that the number of firms that will be required to submit such lists has been grossly underestimated.

In addition, EPA has made no attempt to estimate the cost of continued compliance with the proposed regulations. Alcoa

understands that the proposed regulations would not impose a one time obligation. However, EPA's "Reports Impact Analysis" is silent on the matter; it apparently considered only the projected cost of the initial searching, copying and listing that would be required on the regulations' promulgation. A limitless number of substances and mixtures may be added to the list by EPA. Each addition to the list will necessitate researching a company's files at each of its locations. Projected compliance costs must reflect much more than just the initial search, because that process will necessarily be repeated each time EPA amends the list of substances and mixtures contained at 40 CFR 716.13.

Finally, Alcoa alone estimates that under the proposed regulations it might incur costs as great as $25,920 for the initial file search alone, which would include only Alcoa's corporate headquarters' and plant locations' current files. The cost of accessing approximately 33,600 cubic feet of archieved files, which would be required under the proposed regulations, is not included in that figure. The cost of education of responsible employees and establishment of internal procedures to assure compliance with the regulations, and compilation and copying of materials for the Agency would be additional. Accordingly, Alcoa believes EPA's estimate to be extremely inaccurate.

Further, Alcoa believes that the volume of data which will be required for submittal to EPA under the proposed rule will result in extreme burdens upon the Agency in terms of time required for evaluation and professional expertise for study assessment. Alcoa believes that costs to the Agency itself would be much in excess of the estimated $411,000.

Accordingly, Alcoa takes exception to EPA's position that a Regulatory Analysis is not required and maintains that the economic impact of the proposal should be reexamined by the Agency.

ETN-227