



A/C Pipe
Producers Association

Internal Correspondence

TO

FROM

SUBJECT

Board of Directors
International Affairs Committee

J.F. Welch
J.F. Welch, Vice President

DATE

August 7, 1984

U.S. Environmental Protection Agency (EPA) - Advance Notice of Proposed Rulemaking
on National Revised Primary Drinking Regulations

REF: JFW correspondence, same title, July 6, 1984

ACTION REQUIRED: Review for information

Current Status

As mentioned in the above reference, EPA's Office of Drinking Water requested the Agency's Science Advisory Board to review evidence on the toxicology of ingested asbestos. Enclosed is correspondence from the Office of Drinking Water to the Science Advisory Board requesting the Board's assistance. The complete document is not provided because it is merely a recapitulation of information previously routed.

At Staff's request, Kirkland and Ellis monitored the Science Advisory Board meeting and summarized the discussion (see enclosure). According to special counsel, "The general consensus was that the ingestion risk was low to zero, but no one was quite willing to dismiss the (occupational) cohort GI cancers."

Also note that Dr. Joseph Cotruvo (Director of Criteria and Standards, Office of Drinking Water) reports that "nodules" have been found in chrysotile-fed rats in the National Toxicology Program (NIEHS) feeding study. Staff will determine the significance of these findings and advise by separate memo.

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

JFW/lk

Enclosure

cc: A.H. Kahn, Esq.
Timothy S. Hardy Esq. w/o enclosures

copies to:

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SUBJECT: Risks From Ingestion of Asbestos Fibers in Drinking Water

FROM: Victor J. Kimm, Director
Office of Water (WH-550)

TO: Terry F. Yosie
Science Advisory Board (A-101)

In the course of preparing revised National Primary Drinking Water Regulations, EPA's Office of Drinking Water is evaluating the toxicology of numerous substances including asbestos fibers in drinking water. The pivotal question in the case of asbestos is whether or not there is a sufficient basis to conclude from the existing animal and epidemiological data whether ingestion of these fibers would increase the risk of gastrointestinal or other cancer in humans.

We have summarized the literature in the attached report and identified four issues that we request the SAB to address:

1. Do existing animal and epidemiological data provide a sufficient basis for a conclusion as to whether or not ingestion of asbestos fibers in drinking water would increase the risk of gastrointestinal or other cancers in humans?
2. Is there a physiological basis for quantitation of human risk associated with the ingestion of asbestos in drinking water from the results of animal data or case control and cohort studies of occupationally exposed population?
3. If inhalation of asbestos fibers during occupational exposure has led to increased risks of GI cancer, is it reasonable to assume that this was caused by swallowing inhaled fibers or are there other possible mechanisms such as: promotion or initiation.
4. If there is a sufficient basis for concluding that ingestion of asbestos fiber in drinking water increases the risk of GI or other cancer, what would be the basis for determining the no adverse effect level with an adequate margin of safety?

Several documents are included for additional background information.

We thank you for your assistance and guidance.

Attachments

Major Issues Associated with Health Effects of Asbestos

~~in Drinking Water~~

(Carcinogenesis of Ingested Asbestos Fiber)

for

Science Advisory Board

Environmental Health Committee

Criteria and Standards Division
Office of Drinking Water

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provide constructive comments regarding what the document should be.

To this comment, Dr. Corn responded that he thought Dr. Crump had done a "beautiful" job of putting together the issues that had been considered here, and he felt that Dr. Crump's document was a sample of what would be acceptable to the Board. He said that Crump's document was an excellent model for placing issues in appropriate perspective.

Dr. Nicholson then gave a brief response. He felt that there was insufficient evidence to allow one to distinguish among fiber types. He said his document was not designed to deal with GI cancer; instead, it was designed to deal with air quality; and he said that GI cancer was an open issue.

II. Major Issues Associated with Health Effects of Asbestos in Drinking Water.

Dr. Cotruvo gave the introductory remarks and highlighted the major issues and conclusions. He said that the principal question in this area was whether existing animal and epidemiological data provide a sufficient basis for a conclusion regarding the relation between ingestion of asbestos fibers in drinking water and increased risks of gastro-intestinal or other cancers in humans? If so, then we need ask how this risk can be quantified. Also to be considered are the physiologic mechanisms involved, and

finally, how one can determine the safe or de minimis level of exposure.

Dr. Cotruvo then summarized data from three different types of studies: animal studies, epidemiological studies and occupational studies. Animal data suggest that there is no increase in toxicological risk from animals resulting from ingestion of fibers. However, he noted that the recent study conducted by the National Toxicology Program (NTP) with chrysotile in rats may have produced some nodules in the lower GI tract resulting from ingestion of asbestos. These data are new and they will be discussed in North Carolina on Friday, July 27, 1984.

Epidemiological data suggest no increased cancer risks associated with the presence of asbestos in drinking water. While the San Francisco study originally indicated gall bladder, pancreatic and peritoneal cancer resulting from ingestion of asbestos fibers, later statistical analysis did not bear out these results. These results are now attributed to confounding factors such as smoking. Dr. Cotruvo emphasized the importance of realizing that epidemiological studies are not very sensitive in terms of showing a relationship between such a small risk and health effects.

Many occupational studies demonstrated an increased risk of cancer of the GI tract. If these apparent risks are valid, there are two issues to be discussed: (1) Is the

- effect relevant to the ingestion of drinking water; and
(2) What is the mechanism involved?

Following Dr. Cotruvo's overview, Dr. Lamm gave a brief statement. He said that there was concern about asbestos fiber type, and in many of the water studies the fiber type was not identified. He then called attention to the fact that at the OSHA hearings, EPA announced submission to OMB of a proposal banning asbestos in cement pipe. He said that this position should be reconsidered. He said that EPA based this proposal on U.S. studies and comparative risks in the U.S. He pointed out that in developing countries, asbestos cement pipe was used, and health problems in developing countries would be compounded if asbestos were banned.

Board Comments

Dr. McDonald: Noted that epidemiologists would have difficulty accepting the studies that were reviewed in this document, in view of the fact that we are looking for very small factors in the presence of many confounding factors. He suggested that what is needed is a very carefully controlled study with a large sample of individuals. However, he noted that the cost of such studies might be prohibitive. He then talked about the analysis of thirty occupational studies, eighteen of which demonstrated an excess level of GI cancer. Twelve of the studies however showed either a

lower-than-would-be-expected incidence of GI cancer, or no increase in GI cancer.

Dr. Mossman: Said that the occupational data were controversial. She said that the animal data demonstrated that the carcinogenic potential for GI cancer was either low or very weak. She reiterated the importance of separating cancer into the site of origin, which is not done in the document. She also questioned the possibility that asbestos might be a cocarcinogen. She discussed the NTP study where animals were given a known carcinogen along with asbestos, and there was no resulting increase in tumors above what would have resulted from the known carcinogen itself. In other words, there was no synergism between the known carcinogen and asbestos ingestion.

Dr. Weiss: Asked to what extent the negative evidence is a result of varying lengths of fiber. He also questioned whether there is some type of immune system compromise in people occupationally exposed to asbestos that could account for the results obtained in the occupational data.

Dr. Doull: Argued for a consolidated health assessment document. He said that there was no need to have a separate health assessment document for each office in EPA. He did not feel comfortable arriving at a decision saying that the evidence is one way or another, in light of the questionable occupational study data.

Dr. Kuschner: Reiterated the importance of separating out the tumors according to site of origin. He said that the GI tract is very sensitive to changes in diet, to changes over time, and also to ethnic variations. He noted that there is a vast difference in etiology, not only of upper and lower GI cancer, but also of specific types of upper GI cancer and lower GI cancer (for example, variations in etiology of stomach and esophageal cancer). In light of this, even the occupational data were not convincing.

Dr. Schull: Said that he was not familiar with the data presented in the paper, but given what he read, he felt that there was little hazard in ingestion of asbestos in drinking water.

Dr. Hackney: Said existing studies do not provide a sufficient basis for determining whether there is a cause-effect relationship between asbestos ingestion and cancer. He noted that the situation in this instance is different from the normal situation. Here there are positive epidemiological data but negative animal data. In contrast, the usual situation involves positive animal data but negative epidemiological data. The good negative animal data should be carefully considered; he felt that there is little scientific basis for regulating on the basis of ingestion. He said that the animal and epidemiological data suggest that

the inhalation data are not relevant to community regulation of drinking water.

Dr. Abramson: Noted that the document should make Dr. McDonald's point regarding the evidence from occupational studies.

Dr. Corn: Made reference to an English paper by Commins, entitled "Asbestos Fibers In Drinking Water," said that this was a very good review with a number of citations; said that this paper reaches the some conclusions about the questions posed in the document at hand here.

Dr. Weiss: Seemed very concerned about the possible results of the NTP study. He questioned whether the study had considered various fiber types or controlled for diet.

The Board was asked to submit written comments regarding this paper. Comments and recommendations will then be drafted and forwarded to the EPA Program Office.