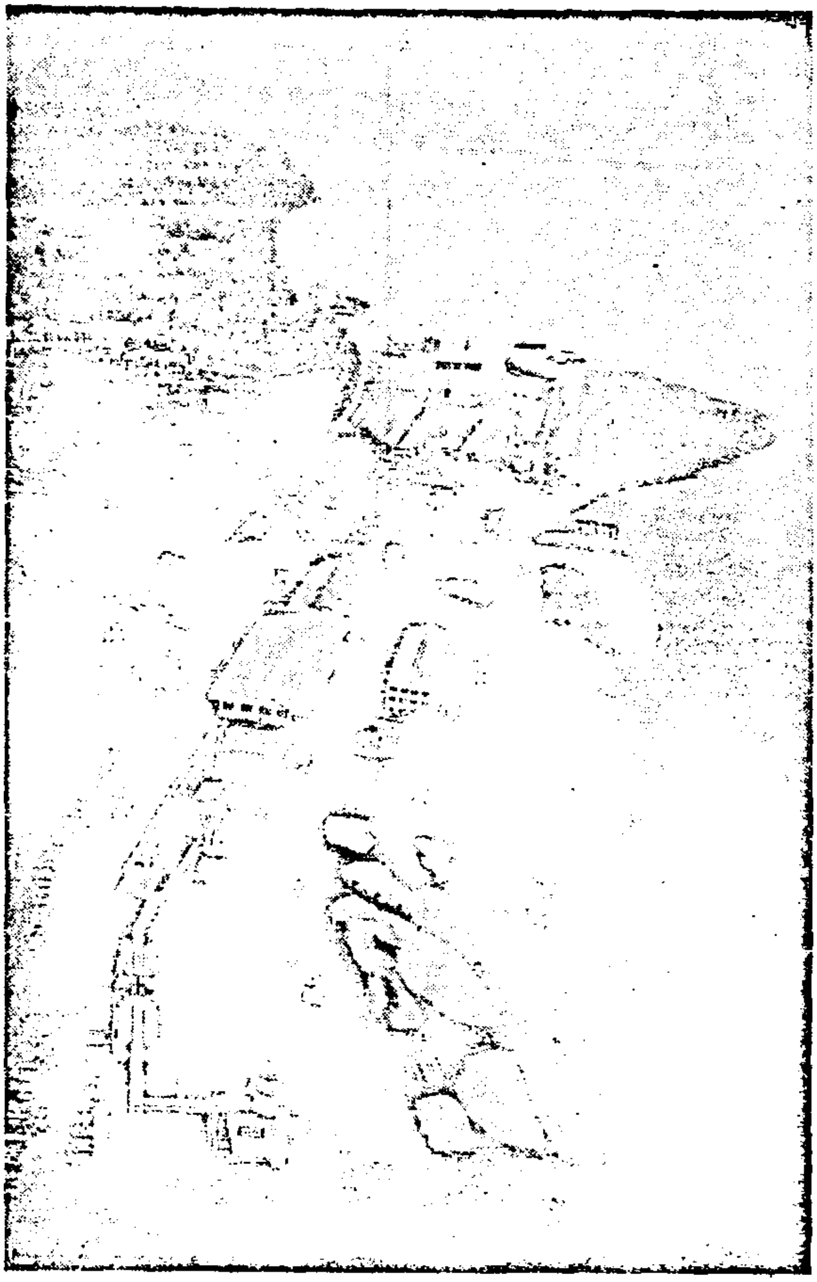

American Smelting and Refining Company photo

All processing of arsenic in the United States is done at the Tacoma plant of the American Smelting and Refining Company.

Arsenic, Industry And Cancer

By Bill Richards and Rachel Scott

Richards is a Washington Post metropolitan staff writer. Scott, whose book, "Muscle and Blood," was published last year, is director of health and safety for the Illinois Industrial Commission.

ARSENIC has claimed a certain notoriety over the years as a parlor room poison—death by the teacup, administered by smiling spinsters seeking to polish off their victims in as gracious a manner as possible. But there is nothing gracious in the deadly evidence beginning to emerge, far from the lace and the china teacups, that arsenic causes cancer and that a million or more American workers may be unwittingly putting their lives on the line through daily exposure to the chemical on the job.

Concern began growing last summer when two of the chemical industry's giants—the Dow Chemical Company and the Allied Chemical Corporation—admitted in an unusual display of corporate candor that workers who once handled inorganic arsenic at their Midland, Mich., and Baltimore pesticide plants were dying of lung and lymph cancer at an alarming rate.

Allied reported that among workers retired from its Race Street plant in Baltimore lung cancer was seven times that of other males in the city and lymph cancer rates were six times higher than expected. Dow's separate study at its now-closed Midland plant revealed a 32.9 per cent cancer rate among workers exposed to inorganic arsenic in the 1950s.

While the numbers covered by the studies are relatively small the implications for industry are enormous. Some federal health experts now concede that the inorganic arsenic menace may be as substantial in the workplace as that posed by the more widely publicized vinyl chloride cancer connection discovered a year ago.

Inorganic arsenic is a byproduct of the smelting process. Some 15 copper, lead and zinc smelters ship it to the lone processor in the United States, the Tacoma, Wash., plant owned by the American Smelting and Refining Company (ASARCO). Arsenic trioxide, an inorganic arsenic compound that is the most widely used form of the chemical, shows up in at least 44 different major industries by a federal count, from tinting windshields in Toledo to spraying roses in Texas. The United Steelworkers Union alone estimates that 40,000 or more of its workers may be exposed. Federal estimates of exposed workers run to 1.5 million.

While there are substitutes for arsenic in some secondary industries the most seriously exposed workers—in copper and lead smelters where inorganic arsenic is a major byproduct of the smelting process—are virtually condemned to further exposure, if industry spokesmen are to be believed.

In pleas to federal regulatory officials to keep the present exposure standards—which were in effect for Allied workers—the metal smelting industry claimed any change at this point would be economically disastrous.

Missed Signals

IT IS HARDLY any secret that arsenic can cause cancer. The first suggestion that it might be a carcinogen was raised in 1820. But the Allied and Dow disclosures pose the cardinal question—why were workers exposed to hazardous amounts of arsenic in the first place?

Norman Herington, a spokesman for Allied Chemical, recently supplied one answer. "I'm sorry to tell you," he said, "that until 1973 we didn't have any suspicions that the conditions existing at (Allied's Baltimore plant) were causing cancer." According to Herington, "none of the manufacturers who were making arsenical compounds had any indications" there were cancer problems associated with inorganic arsenic.

Curiously, Allied, Dow, ASARCO and the other manufacturers, with billions of dollars in resources and stables of researchers, apparently managed to miss, or ignored, some disturbing warning signs—reports stretching back to the 1930s linking arsenic with several types of cancers.

"This isn't something new that is just bursting out," Dr. J. William Lloyd, a biostatistician for the National Institute for Occupational Safety and Health, said recently. The reason the companies missed the warning signs, said Lloyd, was because "nobody was looking. Sometimes because they didn't want to look, and sometimes because they didn't think to look."

A few of the missed signals included:

- Reports dating back to the 1930s of suspiciously high skin cancer rates among persons who had inorganic arsenic compounds prescribed for skin ailments. One study in 1968 noted that 21 skin cancers were observed among 180 patients who used inorganic arsenic preparations.
- Findings by British researchers in 1948 that high lung and skin cancer rates were turning up among factory workers involved in the manufacture of sheep dip, containing inorganic arsenic.
- A 1959 study of workers at an English nickel refinery, where ores contained a high arsenic content, showing 45 cases of lung cancer and two of skin cancer over a decade.
- A study in 1969 by Drs. Frederick P. Lee and Joseph F. Fraumeni, of the National Cancer Institute, of 8,047 American metal smelter workers. The workers showed a threefold excess of respiratory cancer mortality and, when they were heavily exposed for long periods to inorganic arsenic, as much as eight times the expected mortality rate.

Basis for Standards

THE CORNERSTONE study, however, accepted until recently as indisputable evidence on the potency of arsenic and used as the basis for the present arsenic exposure standards, was done by Dr. Sherman Pinto in 1963. Pinto's research team studied 229 deaths among copper smelter workers exposed to .5 milligrams of inorganic arsenic per cubic meter of air at ASARCO's Tacoma plant—the current federal exposure standard—and compared them to other workers at the smelter who he claimed were not exposed. He discovered almost no difference between the two groups and concluded that chronic exposure to arsenic did not cause excess amounts of respiratory cancer.

Industry quickly pounced on the study done by Pinto—who was then medical director of the same ASARCO plant in Tacoma—disregarding the contrary evidence.

Worse still, Pinto's findings became the basis for the present federal standards for inorganic arsenic exposure after they were accepted by the American Conference of Governmental Industrial Hygienists (ACGIH), a quasi-official body which, until 1970, was the only organization setting standards for toxic dusts and fumes in the workplace.

The ACGIH standards were incorporated into the old federal Walsh-Healey Act, which regulated working conditions for plants operating under federal contracts, and were adopted by the states in their regulations as well. With the passage of the Occupational Safety and Health Act of 1970, the Pinto-based standards were again called upon.

Despite the reliance on Pinto's data by the ACGIH and later the Occupational Safety and Health Administration (OSHA), which adopted the current federal arsenic standards, a number of federal investigators are now convinced that the Pinto findings are seriously flawed.

As early as 1969, Lee and Fraumeni pointed out in their study that Pinto's conclusions compared exposed and non-exposed smelter workers but neglected one critically additional step—Pinto failed to compare his two worker groups with others outside the

plant. The two researchers noted that while Pinto seemed correct in saying there was little difference between cancer levels inside the smelter, the plant population as a whole showed lung cancer rates as much as three times the general population.

Pinto, contacted last week by The Washington Post, acknowledged that no comparision had been made in his study with people outside the plant. "The criticism has been raised about non-exposed people," he said. "I don't believe it too much. I don't pay much attention to it."

ASARCO Assurances

AT THE LATEST round of federal hearings last September to explore new exposure standards for inorganic arsenic, ASARCO showed up as the major arsenic industry witness, with a panel of experts including Pinto, now a semi-retired consultant to the giant smelting company. Prudently, Pinto kept in the background and let ASARCO's other spokesmen assure the federal representatives that there was little cause for alarm and certainly no reason to tighten up the prevailing standards.

ASARCO once again hauled out the original Pinto study, saying that the findings, and an update also done by Pinto, indicated there did not seem to be any increased mortality from arsenic exposure among the Tacoma smelter workers. With this, ASARCO called for retaining the current exposure standard and suggested an independent study of the findings of their colleagues at Dow and Allied.

What they neglected to mention was that in addition to the heavy criticism of the original Pinto study the update was attacked last year by Dr. Samuel Milham Jr., a chronic disease epidemiologist for the Washington State Health Department, for its lax handling of statistics.

Milham pointed out that Pinto neglected to include in his study of smelter workers the secondary cause of death listed on death certificates. If a worker had pneumonia on his death certificate as the primary cause of death Pinto listed that—and skipped the notation that the man also had lung cancer. "We found that he missed 25 per cent of the lung cancers at a conservative estimate," Milham said. In fact, instead of the 18 lung cancers predicted by standard mortality tables for Pierce County, Wash., smelter workers, Milham discovered 40.

Asked about Milham's findings, Pinto said, "In my own mind I'm quite sure that my material is accurate." Nevertheless, he said he had turned over all the material he had on deaths to Dr. Philip Enterline, professor of epidemiology at the University of Pittsburgh, for an "outside" analysis.

"The criticism has been raised that I'm not a professional codifier so now the information is in the hands of a professional. He's a highly regarded expert in his field and I think industry is doing the right thing when they get an unbiased opinion like his."

Enterline, Pinto noted, received a contract seven years ago from ASARCO to do consulting research for the company. The choice of the Pittsburgh researcher this time was suggested, according to Pinto, by ASARCO's vice president, Kenneth Nelson. It was Nelson who testified at the OSHA hearing last fall for ASARCO in defense of Pinto's earlier findings.

Nelson told the OSHA investigators at the hearing that a decision to cut back on exposure levels among its workers could be financially ruinous for the company and later said it could force the shutdown of lead and copper smelters throughout the West.

"There is absolutely no conflict of interest (in the choice of Enterline)," Pinto said last week. "He would be the first to tell me if I were wrong."

The "22 Milestones"

WHAT HAPPENS now concerning arsenic is up to OSHA, but the preliminary indications are not encouraging. In an interim report following the hearing the National Institute for Occupational Safety and Health, OSHA's own research arm, flatly declared that inorganic arsenic is a carcinogen and "any exposure to inorganic arsenic in excess of background levels should be considered an unacceptable risk" until new data are available.

OSHA dutifully accepted their comments, filed them away, and embarked on what is known in the agency as the "22 milestones"—the steps it must take before setting out a permanent standard for arsenic exposure. Among those steps is the consideration of relevant research data on arsenic. OSHA staffers handling the project acknowledged recently that high up on the list of research still considered "significant" are the two Pinto studies.

Moreoever, there appear to be strong indications that OSHA may end up compromising the safety of workers exposed to inorganic arsenic for the economics of the chemical and smelting industry.

"Whatever we do must be feasible, regardless of what NIOSH recommends," James Foster, a spokesman for OSHA, explained recently. "NIOSH specifically deals with the scientific, medical and technical aspects of this. On the other hand it's our job to look at what this is going to cost industry as well as those other things."

No matter what OSHA decides to do, traveling the 22 milestones is certain to take the agency far into 1975 before any tougher standard is set to protect workers from a known carcinogen. And almost certainly the process will involve another public hearing and yet another appearance of Dr. Sherman Pinto and his arsenic study.

THE WASHINGTON POST

Wednesday, Jan. 29, 1975

Court Raps EPA On Gas Lead Rule

By Timothy Robinson
Washington Post Staff Writer

The Environmental Protection Agency has failed to prove that lead spewed into the air from automobile exhausts causes a significant health hazard, and therefore its regulations phasing out the lead content in gasoline must be set aside, the U.S. Court of Appeals explained here yesterday.

The court, aligned 2-to-1 against the EPA guidelines, issued a brief ruling setting aside those regulations Dec. 23. Yesterday's opinion explained in detail the reasoning behind that earlier ruling.

The regulations had been described as among the most important passed by the environmental agency. They would have required the overall content of lead in gasoline to be reduced by approximately two-thirds by 1979.

Gasoline refiners had opposed the regulations, claiming that lead additives provide them with the flexibility to produce gasoline with differing octane ratings with a minimum of refining and processing equipment. The refiners also claimed that production of higher octane gasoline without the use of lead would require greater amounts of scarce crude oil.

The refiners had argued in the court suit that the EPA had used an improper legal basis for drawing up the regulations, that the evidence did not support EPA's concern for the public health, and that the case against auto lead emissions "is a speculative and inconclusive one at best."

U.S. Circuit Court Judge Malcolm Wilkey agreed with the refiners' arguments in a 73-page majority opinion, in which he was joined by Judge Edward Tamm.

The EPA administrator had based his authority to issue the regulations on statutory grounds that enable him to prohibit the use of fuel additives that "will endanger the public health or welfare."

Judge Wilkey said any decision under that authority to prohibit the sale of additives must be based specifically on facts, and not conjecture.

"We think that the statute does require that, before the administrator can prescribe the regulations involved here, he must find that the lead from auto emissions by itself or alone contributes a measurable increment of lead to the human body, and that this measurable increment causes a significant health hazard," Judge Wilkey said.

Studies have shown that lead from automobile emissions contributes to the problems of lead in the blood of adults and children, but the majority opinion said the studies did not prove that lead from gasoline was a significant health factor.

"Several vital links in the chain are unsupported; for the administrator to leap to the conclusion he did can only be termed arbitrary and capricious," Judge Wilkey said.

"We think this brand of administrative agency action should be readily apparent—and equally abhorrent—to any appellate judge," he said, adding that the function of a reviewing court is to "detect and set aside agency action based on such shoddy foundations, not to engage in rival scientific calculations or substitute judgment."

Judge Wilkey commented that the EPA decision was "Hamlet-like, a blind stab through a curtain of ignorance, inflicting anguish, but in our judgment not rationally solving any problem."

U.S. Circuit Court Judge J. Skelly Wright disagreed, sometimes bitterly, with the majority court's opinion.

In his 96-page dissent, he accused the majority judges of "confusing a very important issue."

Each sample, according to FDA, should consist of 24 containers of the same code, if possible. FDA ordered detention of products above the 10 p.p.m. temporary tolerance after check and confirmatory analyses.

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PVC INTERIM REGULATION BASED ON VCM EXTRACTION PREVIEWED

Secretary of Health, Education and Welfare Caspar Weinberger has indicated that the interim Food Additive Order proposed for polyvinyl chloride will be based on a 50 p.p.b. limit on extraction of vinyl chloride monomer, apparently confirming that there will be no limits at the manufacturing level (See FOOD CHEMICAL NEWS, Dec. 16, Page 2).

At various times, the Food and Drug Administration has tended towards limits on vinyl chloride content of the packaging material itself and limits on film thickness. Use instead of a limit on migration using food-simulating solvents has been urged by the Society of the Plastics Industry, and the Weinberger letter -- dated Dec. 13 -- indicates that FDA may use this approach. FDA enclosed a copy of the HEW letter Jan. 9 in responding to an inquiry from Hooker's RUCO Division.

Although the letter indicated that only the extraction limit will be proposed, there is not believed to be unanimity on the subject within FDA's Bureau of Foods.

Weinberger said the draft Federal Register documents would include an interim Food Additive Order proposal to "limit the use of vinyl chloride polymers to only those food-contact applications where the possibility for vinyl chloride extractives in food is essentially zero."

The HEW Secretary said FDA "is currently considering, as one alternative, a proposed interim food additive regulation which would require that there be no detectable migration of vinyl chloride monomer to food-simulating solvents using the most sensitive confirmed analytical procedure available, which FDA believes is presently 50 p.p.b." If improved analytical procedures are developed later, he said, lower levels "would then be proposed by FDA for a new standard approaching zero."

Data to be Required on PVC

Weinberger revealed that FDA's draft documents "would also require prompt initiation of appropriate animal feeding studies with periodic submission of progress reports, and require the submission of other scientific data including validated analytic methodology, levels of residual vinyl chloride monomer in PVC food-contact articles and levels of vinyl chloride extractives." The Secretary continued:

> "The major problem confronting FDA in the preparation of the new draft proposals has been the lack of a sound scientific basis for a definitive decision. Although vinyl chloride has been shown to be carcinogenic by inhalation, there is very little information concerning its effect upon

ingestion. The FDA knows of no studies which establish a safe level of consumption when this monomer is leached from containers into packaged foods.

"Therefore, until such time as there is a sound scientific basis for a definitive decision, FDA believes it is necessary that they propose, on an interim basis, to limit further food-contact use of polyvinyl chloride to only those uses where the possibility for migration of vinyl chloride monomer to food approaches zero and represents negligible levels in the diets of consumers."

Weinberger wrote that FDA has been investigating analytical methods to "establish the lowest level that can be determined using various food-simulating solvents," and that there have been "a few reports of quantities of 20-30 p.p.b. vinyl chloride extractives detectable by existing methodology." However, he added that FDA studies "have indicated that in the hands of qualified analysts a reading of 50 p.p.b. ... is the lowest that can be reported with confidence."

The Secretary's letter was in response to Sen. Tunney (D-Calif.), who asked clarification of testimony given before the Senate Commerce environment subcommittee (See FOOD CHEMICAL NEWS, Aug. 26, Page 2). He asked Weinberger to "explain what FDA proposes to do in regard to polyvinyl chloride food packaging, and the scientific and legal justifications for setting a non-zero tolerance for vinyl chloride in polyvinyl chloride food packaging, foods, drugs and cosmetics, if that is in fact your intention."

The Senator also asked for information on FDA's decision to ban packaging of alcoholic beverages in PVC containers, plus "any recommendations which may have been made to FDA by SPI concerning particular non-zero levels of vinyl chloride which might be acceptable in beverages, and the scientific and legal justification for any such recommendations."

VCM Found in Vegetable Oil Ranges From 0.1 p.p.m. to 9 p.p.m.

Tunney asked for levels of VCM found to leach in consumer products. FDA analyses have shown VCM in vegetable oil packaged in PVC ranged from 5 p.p.m. to 9 p.p.m. for a 3-year-old sample, and from 0.1 p.p.m. to 0.2 p.p.m. in a 6-month-old sample. No VCM was detected in samples of blood bags and anticoagulant solutions, but some brands of mouthwash showed the monomer in amounts ranging up to 7.9 p.p.m.

Hooker's RUCO urged that FDA "avoid any precipitous action which might unnecessarily disrupt the safe and successful use of PVC in food packaging applications," saying: "Should regulation be deemed advisable with the advent of feeding test data, then the extent to which vinyl chloride becomes a food additive should be the controlling factor and not product specifications such as wall thickness, trace composition concentrations, etc."

The firm said vinyl chloride content of the packaging material need not be regulated, since "the prime function of the FDA is to obviously deal with food additives." Hooker

said that "a PVC compound is not a single formulation and therefore the primary concern should properly be limited to the food additive behavior and not include product specifications which have complex relationships to potential migration."

Opposing any limit on wall thickness, the firm said this "could arbitrarily legislate out of existence many useful and safe PVC packages," adding that "the only equitable test of suitability ... must be the extent to which a suspect ingredient becomes a food additive in a real-life situation."

Noting the lack of ingestion data on the effects of VCM in foods and the absence of any instance "where harmful effects have been attributed to the consumption of food packaged in PVC containers," Hooker asked, "What would be the rationale, therefore, of setting extremely low allowable limits, in parts per billion, on vinyl chloride monomer in food products?" The company urged that FDA "await evidence on the results of feeding tests before promulgating restrictive and disruptive regulations."

FDA Deputy Associate Commissioner for Compliance William F. Randolph replied on Jan. 9 that the "draft proposed regulations are still under review at the FDA Bureau level," suggesting that Hooker might want to arrange a meeting with representatives of the Bureau of Foods.

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FDA EXPECTED TO STICK WITH PROPOSED BAN ON ANTIBIOTIC COMBINATIONS

The Food and Drug Administration is expected to stick with its revised proposal to ban combinations of low-level antibiotics on which required data has not been submitted, despite industry comments urging that the proposal be replaced by another revision (See FOOD CHEMICAL NEWS, Dec. 23, Page 33).

Agency officials conceded that comments pose a serious question regarding the legality of banning the combinations without first offering an opportunity for a public hearing. In comments it has been contended that the products are covered by New Animal Drug regulations or their equivalents which cannot be revoked without formal procedures. This question will be put to FDA attorneys in its General Counsel's office for a determination.

Many comments contended that §135.109 of the regulations, which is being invoked in the proposal, pertains only to animal drugs used for non-therapeutic purposes, whereas some of the combinations proposed for banning are therapeutic.

In attempting to resolve the question of when a product becomes "therapeutic," FDA-ers have stated that a product is non-therapeutic and is covered by §135.109 if it is used continuously for more than 14 days. Agency spokesmen say that firms cannot avoid the review of low-level antibiotic products simply by increasing dosages and including the "for the treatment of" phrase in labeling.

Regarding the errors of omission and commission alleged in many comments, FDA-ers say the proposal and the comments are being carefully reviewed to pinpoint any such errors and to eliminate them.

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