



ACTION ALERT

THE REFRACTORIES INSTITUTE
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July 18, 1978



To: The Official Representative of Each
Active and Associate Member Company
in the United States:

Subject: PRELIMINARY CLASSIFICATION OF
SUSPECTED CARCINOGENS

The day after the Institute's testimony at the OSHA hearings on suspected carcinogens, OSHA released its long-awaited preliminary classifications. While these lists are only tentative and subject to change as the rulemaking process continues, they do give us the first authoritative indication of how chemical substances in use in the refractories industry may be controlled.

I am attaching a list of OSHA's proposed Category I, II and III classifications for chemicals reported by members of the TRI Safety and Health Committee as being in use in the industry. There are 14 substances classified as Category I, five as Category II, 22 as Category III, and one (Silica) classified both as Category II and III---a situation I am trying to clarify.

Needless to say, I was disappointed to see so many Category I classifications for our industry. Chromium compounds received more attention than I expected, but coal tar and coal tar pitch compounds received less. Remember, however, that these are only tentative classifications.

CATEGORY I

Exposure to substances classified as Category I is considered to constitute "a grave danger" and such chemicals are proposed to be regulated most stringently, first under an emergency standard, then under a permanent standard designed to reduce workers' exposure to the "lowest feasible level" or possibly zero if substitutes are available. Activities required of manufacturers or processors by the proposed permanent standard include (i) exposure monitoring and measurement; (ii) regulated (limited access) areas; (iii) control through engineering and work practices; (iv) respiratory protection; (v) protective clothing and equipment; (vi) housekeeping; (vii) waste disposal; (viii) hygiene facilities; (ix) medical surveillance; (x) employee training; (xi) precautionary signs and labels; and (xii) recordkeeping. The extent of these activities would be similar to those discussed at the May membership meeting in connection with the proposed silica standard, but the cost impact would probably vary from substance to substance.

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CATEGORY II

Category II substances are potential carcinogens for which the evidence is "only suggestive" rather than convincing. They would be regulated less stringently, but the regulation would require most of the activities mentioned above in one form or another. A major difference is that exposure limits, instead of being at the "lowest feasible level", are to be set at the level of existing OSHA standards (29 CFR 1910.1000), or (where none exists) at "an appropriate level based upon acute or chronic effects of exposure...other than carcinogenicity", or, if the present OSHA standard is inadequate to prevent those effects, it shall be lowered by the Secretary to an "appropriate" level. Also, there is no emergency standard provision for Category II substances, nor a requirement for regulated areas, nor the need for special lunchrooms. The difference in the cost of compliance for a Category I classification compared to Category II for a given substance could vary from trivial to catastrophic, depending upon the difference, if any, between an "appropriate level" to prevent acute or chronic effects from exposure and the "lowest feasible level".

CATEGORY III

Category III substances require no special new controls but since they are recognized toxic substances there may already be recommended or regulated exposure limits which should still be followed. Category III substances can of course, be upgraded to II, or II to I, if new test results or other convincing scientific information is forthcoming.

STRATEGY

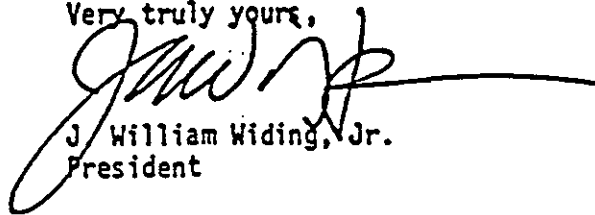
If the OSHA procedure is adopted as proposed and these classifications are upheld, it is obvious that many extremely expensive and far-reaching changes in how the industry does business will be required. This is not the time to throw in the towel, however. It is the time to get to work on developing a counterstrategy. If you have any data on these Category I or II classifications which would indicate they are incorrect (overly stringent), now is the time to get it together. In fact, if you can get such information in my hands by August 1, I can have it included in the post-hearing record. Of particular interest here is the question of whether Chromium (III) should be controlled to the same degree as Chromium (VI), as well as the question of whether either deserves a Category I classification.

Beyond that, it will take further discussions and planning to decide how TRI should respond to these initial classifications. One thing seems clear to me, however, and it is this: we stand a much better chance of softening their impact if we start work immediately instead of waiting for OSHA to publish final classifications. The time for response later when a notice of proposed rule-making appears in the Federal Register will be far too short to accomplish anything of significance.

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I would appreciate hearing from each member who expects to be affected by these classifications as quickly as possible during the post-hearing comment period.

Very truly yours,

A handwritten signature in dark ink, appearing to read 'J. Widing', with a long horizontal flourish extending to the right.

J. William Widing, Jr.
President

JWW/hm

cc: Environmental Protection Committee
Safety and Health Committee
Technical Advisory Committee
Toxic Substances Subcommittee
H. W. Fulton, Jr.

PRELIMINARY CLASSIFICATION OF
SUSPECTED CARCINOGENS
REPORTED BY SOME REFRACTORIES PRODUCERS

CATEGORY I

Acetic acid, Lead (2+) salt
Asbestos
Benzene
Carbon Tetrachloride
Chromic acid, Chromium (3+) salt (3:2)
Chromic acid, Dipotassium salt
Chromic acid, Disodium salt
Chromite
Chromium
Chromium (III) oxide (2:3)
Chromium (VI) oxide (1:3)
Ethylenediamine, N,N'-Dimethyl-
N,N' Dinitroso
Serpentine
Tannic acid

CATEGORY II

Ethyl alcohol
Iron (III) oxide
Petroleum
Petroleum asphalt
Phenanthrene
Silica, Crystalline (also Category III)

CATEGORY III

Anthracene
Boric acid
Brucite
Cellulose, Carboxymethyl ether,
Sodium salt
Cobalt (II) nitrate (1:2)
Cobalt (2+) oxide
Ethylene oxide
Fluorescein, Disodium salt
Hexamethylenetetramine
Iron (II) sulfate (1:1)
Magnetite
Mercury
9-Octadecenoic acid (Z)
(Syn: Oleic acid)
Olivine
Phenol
Phenol, Pentachloro-
(Syn: Dowicide G)
Polyethylene
Polyethylene glycol
(Syn: Carbowax)
Polyvinyl alcohol
(Syn: PVA)
Silica, crystalline
(also Category II)
Silver
Stearic acid, Methyl ester
Styrene polymer

administrator has a "heavy burden" to "explain the basis for his decision to permit the continued use of a chemical known to produce cancer in experimental animals." *EDF v. Ruckelshaus* (DOT), 438 F.2d 584, 396 n.41 (D.C. Cir. 1971); accord, *EDF v. EPA* (heptachlor and chlordane), 584 F.2d 998, 1005 (D.C. Cir. 1978), cert. denied, 431 U.S. 825 (1977); *EDF v. EPA* (aldrin and dieldrin), 510 F.2d at 1302; see *EDF v. Department of Health, Education and Welfare*, 428 F.2d at 1000-02. When firm evidence establishes that a chemical is a carcinogen, statutes generally leave an administrator no alternative but to step in to protect the public.

"On the other hand, when the evidence is less than firm, but merely suggests that a chemical may be a carcinogen, the same 'heavy burden' may not attend administrative inaction. The decision to act in such a case has been held to fall within the discretion of the Administrator. For example, in *Reserve Mining Co. v. EPA*, 514 F.2d 492 (8th Cir. 1975) (en banc), EPA sought to abate discharge of mining refuse into Lake Superior "under an acceptable but unproved medical theory," that the discharges were carcinogenic. 514 F.2d at 529. The court concluded that the discharges should be abated, even though there would be a heavy cost, including possible loss of many jobs, to the local economy. Id. at 514-20, 535-40. Similarly, in *Certified Color Manufacturers Association v. Mathews*, 543 F.2d 284 (D.C. Cir. 1976), the Food and Drug Administration (FDA) terminated its provisional approval of a color additive used to dye food on the basis of a vigorously debated study of the additive's carcinogenic effects. This court concluded that the FDA action should be upheld, based upon FDA's scientific judgment that the study was not conclusive, but was merely suggestive of carcinogenicity. Id. at 297. "Courts have traditionally recognized a special judicial interest in protecting the public health, particularly where 'the matter involved is as sensitive and fright-laden as cancer.' Where the harm envisaged is cancer, courts have recognized the need for action based upon lower standards of proof than otherwise applicable." Id. at 297-98 (footnotes omitted) quoting *EDF v. EPA* (DOT), 465 F.2d 528, 538 (D.C. Cir. 1972). The courts have frequently upheld regulations based on evidence of carcinogenic effects. See, e.g., *American Iron & Steel Institute v. OSHA*, No. 76-2354, slip op. at 31-32 (3d Cir. March 28, 1978) (coke oven emissions); *Society of the Plastics Industry v. OSHA*, 509 F.2d at 1311 (vinyl chloride); *Synthetic Organic Chemical Manufacturers Association v. Brennan*, 503 F.2d 115, 1159-60 (3d Cir.) (same), cert. denied, 420 U.S. 973 (1974).

"These cases demonstrate that inevitable tension attending regulation of carcinogens. Frequently, such regulations have severe economic impact. Indeed, sometimes, as alleged by industry petitioners in this case, such regulations may jeopardize plants or whole industries, and the jobs depending on them. In such circumstances, the temptation to demand that the agency furnish conclusive proof of carcinogenicity as support for the regulations is great. However, the decision to delegate authority to an agency to control

suspected carcinogens is a legislative judgment that is not open to question in this court. Congress's direction to EPA to protect against incompletely understood dangers could not be carried out if we were to adopt the proof requirements advocated by industry petitioners."

This proposal marks a departure from OSHA's usual pattern of a substance-by-substance approach in setting health standards concerning exposures to potential occupational carcinogens. For the reasons set forth herein, OSHA believes that such an approach is not only proper and necessary but in fact compelling because of its "experience gained under this and other health and safety laws". (The Act, section 6(b)(5).) Moreover, OSHA believes that by establishing a rational and predictable policy concerning the regulation of exposures to occupational carcinogens, employers, employees, the general public, the scientific community and public interest groups will not only benefit from improved employee health, but also experience greater efficiencies in their own activities."

Employees are exposed to many substances on a daily basis. Obviously, most of these substances are not carcinogenic. Yet, some may be. OSHA believes that this general policy and procedure will facilitate the sifting through the evidence concerning substances which may be imputed to be potential carcinogens and the application of uniform, predictable criteria in order to assess whether such substances should indeed be treated as carcinogenic. Without such a system and appropriate criteria, OSHA believes that this task cannot be accomplished in a timely and efficient manner. With an appropriate system and criteria, worker health will be protected efficiently without rediscovering or relitigating, time and time again, the same issues and without unnecessarily draining limited industry, union, public interest, scientific and government resources. As a result of this policy, OSHA believes that these limited resources will focus on the most

substantial issues in OSHA rulemaking proceedings, thus leading to more compact and useful Records in a shorter period of time. In addition, this policy will result in continuity of approach, even in the face of changes of policymakers. This new approach is intended to ameliorate certain administrative problems in standard setting. One significant aspect of past rulemakings concerning carcinogens was the enormous time period between OSHA's Initial Federal Register notices and final judicial actions. For example, in its nine (9) year history, OSHA has concluded only seven (7) rulemaking proceedings in regulating carcinogens. Moreover, it should be noted that the total time the official process took from the date of the first official announcement in the Federal Register to completion of the judicial review of the final standard does not necessarily include the time required to analyze the facts and develop the proposal in the first instance, which itself can be considerable." Finally, it should be noted that the procedures followed in each of the following cases differed because of an attempt to speed up the process. None of the differing procedures succeeded in achieving that goal.

a. Asbestos

An emergency temporary standard regulating occupational exposures to asbestos was published on December 7, 1971 (36 FR 23207) and not judicially contested; a permanent standard was proposed on January 12, 1972 (37 FR 466) and, after a short hearing, was published in final form on June 7, 1972 (37 FR 11318); the permanent standard was contested in *Industrial Union Department, AFL-CIO v. Hodgson* on July 27, 1972, and affirmed in 499 F.2d

"Only two other health standards have been promulgated during the history of OSHA namely: standards regulating occupational exposures to inorganic lead and cotton dust. In the case of the standard regulating occupational exposure to lead, the proposed final standard was published on October 2, 1973 (40 FR 45934), extensive hearings held and the final standard published on November 14, 1974, a process that took over 36 months. An appeal is pending in the Court of Appeals for the District of Columbia in *Lead Industries, Inc. v. OSHA*. In the case of the standard regulating occupational exposure to cotton dust, an advance notice of proposed rulemaking was published on December 27, 1974 (39 FR 44769), a proposed permanent standard published on December 28, 1975 (41 FR 54496), extensive hearings held in April and May of 1977, and final standards published as to Cotton Dust and Cotton Dust in Cotton Gins on June 23, 1978 (43 FR 27350 and 27418), a process that took over 42 months. Appeals were recently decided by the Court of Appeals for the District of Columbia in *AFL-CIO v. Marshall* and *Texas Independent Ginners Assoc. v. Marshall*."

"While OSHA will not elaborate upon the lengthy time consuming 'case-by-case' rulemakings experienced by other agencies under other statutes, an excellent discussion of the same problems appears in McGarity, 'Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA', 67 Georgetown Law Journal 724 (February 1979). Also see Berger and Riskin, 'Economic and Technological Feasibility in Regulating Toxic Substances Under the Occupational Safety and Health Act', 7 Ecology Law Quarterly 283 (1978). The scientific commentators have also recommended a generic, rather than a case-by-case approach, to regulating carcinogens for the same reasons. See National Academy of Sciences—National Research Council, 'Decisionmaking for Regulating Chemicals in the Environment' 33 (1973).

487 on April 17, 1974, the entire process consuming about 29 months.*

b. Fourteen Carcinogens

On July 6, 1972, OSHA requested information concerning fifteen substances (37 FR 13285). A package of fourteen (14) emergency temporary standards regulating occupational exposures to a like number of carcinogens was published on May 3, 1973 (38 FR 10929), contested in part in *Dry Color Manufacturers' Assn. v. Brennan* and vacated on October 4, 1973 by the Third Circuit Court of Appeals at 486 F.2d 98; an advisory committee was appointed and began its meetings on June 25, 1973, the proposed permanent standard was published on July 16, 1973 (38 FR 18800) and amended on August 16, 1973 (38 FR 22141), a hearing was held in September 1973 and the final standard published on January 29, 1974 (39 FR 3756), contested in *Synthetic Organic Chemical Manufacturers Assn. (SOCMA) v. Brennan I* (EI) on January 3, 1974 and *SOCMA v. Brennan II* (MOCA) on February 4, 1975. In *SOCMA v. Brennan I*, the Third Circuit affirmed in part in 503 F.2d 1155 on August 26, 1974, *cert. den.* on March 17, 1975 in 420 U.S. 973. A petition for rehearing was denied on October 6, 1975. In *SOCMA v. Brennan II*, the Third Circuit affirmed in 505 F.2d 385 on December 17, 1974. A petition for certiorari was filed on March 20, 1975 and denied by the Supreme Court on October 6, 1975 *sub nom. Oil, Chemical and Atomic Workers v. Dunlop* in 423 U.S. 830. The entire process consumed about 40 months.

c. Vinyl chloride

A fact-finding hearing concerning vinyl chloride was announced on January 30, 1974 (39 FR 3874) and held on February 15, 1974. An emergency temporary standard regulating occupational exposure to vinyl chloride was published on April 5, 1974 (39 FR 12341) and not judicially contested, a proposed permanent standard was published on May 10, 1974 (39 FR 16896), the permanent standard published on October 4, 1974, (39 FR 35892), contested in *The Society of the Plastics Industry v. OSHA* on October 1, 1974, and affirmed in 509 F.2d 1301 on January 21, 1975, *cert. den. sub nom. Firestone Plastics Co. v. U.S. Department of Labor* in 421 U.S. 992, on May 27, 1975, the entire process consuming 15 months.

d. Coke oven emissions

An advisory committee concerning occupational exposures to coke oven emissions was appointed on August 12, 1974, and held twenty-eight days of meetings during which testimony was presented by numerous experts and parties and over 200 exhibits received, the proposed permanent standard was published on July 24, 1975 (40 FR 40849), promulgated on October 22, 1976 (41 FR 46742), contested in *American Iron and Steel Institute v. OSHA* on October 23, 1976, and affirmed in 377 F.2d 825 on March 25, 1978, petition for certiorari pending in the United States Supreme Court, the entire process consuming 66 months so far.

e. Arsenic

An advance notice of proposed rulemaking concerning occupational exposures to inorganic arsenic was published on June 11, 1974 (39 FR 20494), a fact-finding hearing was announced on August 30, 1974 (39 FR 31644), held on September 20, 1974, a proposed standard was published on January 21, 1975 (40 FR 3392), a final permanent standard published on May 5, 1978 (43 FR 19384), contested in *ASARCO v. OSHA* on May 3, 1978 and judicial review is pending in the Ninth Circuit Court of Appeals and decision has been deferred pending the result of the Supreme Court decision in the case of the contested standard regulating occupational exposures to benzene, *infra*. The entire ongoing process has therefore consumed 67 months.

f. Benzene

An emergency temporary standard regulating occupational exposures to benzene was published on May 3, 1977 (42 FR 22518), stayed in *API v. OSHA* by the Fifth Circuit Court of Appeals on May 20, 1977, a proposed permanent standard was published on May 27, 1977 (42 FR 27462), published in final form on February 10, 1978 (43 FR 5918), contested in *American Petroleum Institute v. OSHA* on February 2, 1978, and vacated in 561 F.2d 493 on October 5, 1978, certiorari granted in *Marshall v. API* 440 U.S. 906 on February 21, 1979 by the United States Supreme Court, the entire process, so far, consuming 31 months.

g. Acrylonitrile

On June 29, 1977 (42 FR 33043), and July 5, 1977 (42 FR 34328), OSHA requested public comments concerning occupational exposure to vinyl cyanide or acrylonitrile. An emergency temporary standard regulating

contested on January 17, 1978, the stay was denied in *Vistron v. OSHA* on March 28, 1978 in the Sixth Circuit, a permanent standard was proposed on January 17, 1978, (43 FR 45782), hearings held in March and April 1978 and the final standard issued on October 3, 1978 (43 FR 45782). That final standard was not judicially contested, although the entire process consumed 16 months even after the Manufacturing Chemists Association and Dow Chemical Co. on the one hand and E. I. du Pont de Nemours & Co. Inc. on the other hand informed OSHA that such substance was a potential carcinogen based on both animal and human evidence in March and May of 1977 respectively.

h. Beryllium

In the case of a standard regulating occupational exposures to beryllium, the proposed standard was published on October 17, 1975 (40 FR 4814). Hearings were held during August and September 1977. A final standard is pending with the process to date having consumed at least 31 months.

In sum, OSHA believes that the length of time consumed in official regulatory and judicial processes will be shortened after the promulgation of this Part for the following reasons: the periodic announcement of regulatory priorities and advance notice of identification and classification criteria will enable all participants in the regulatory process, including OSHA staff, to act with greater efficiency and certainty in framing the truly critical issues in any rulemaking and locating the required technical and scientific expertise early in the proceeding. This should shorten and sharpen the rulemaking. Also the reviewing courts will be presented with rulemaking records of improved coherence, relevance and reduced size, aiding their deliberations.

Other administrative problems faced by OSHA in promulgating regulations in this area on a case-by-case basis are expected to be mitigated by these regulations. OSHA had stated that the present system unreasonably takes the time of scientific experts who were asked to present statements concerning identical issues in various proceedings. For example, Dr. Rall (Director, NIEHS) testified:

"... I think the discussion of the issues can and should continue forever.

Mr. Hanson [of Dow Chemical Co.] Which forum, sir?

Dr. Rall: In scientific forums. Sometimes the regulatory agency has to say—and I think it is perfectly proper—that we accept the current state of knowledge and regulate on

*The cancer-causing properties of asbestos were