

The panel will be composed of independent experts who will make recommendations to FDA. In addition to the experts (doctors & scientists), who will be voting members of the panel, there will be a non-voting consumer member & a non-voting industry member.

Nominations for the consumer member should be sent to Alexander Grant, Director, Consumer Affairs, Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

After FDA receives the consumer nominations, a list of nominees will be compiled & sent to interested consumer groups or organizations with a voting sheet. The nominee with the highest number of votes will be the consumer representative for the panel.

Persons sending in names for consideration should include:

- A brief review of nominee's activities;
- A statement indicating whether nominee would represent a group or organization.

In addition to nominations to the panel, FDA is asking for both published & unpublished data on the safety & effectiveness of blood & its components.

Details—*Federal Register*: Dec. 13, 1974, page 43413; Nov. 20, 1973, page 32047. Send 12 copies of data about blood safety to Food & Drug Administration, Bureau of Biologics, Office of Efficacy Review, 8800 Rockville Pike, Bethesda, MD 20014. Feb. 11 is deadline for submitting data.

Canned grapefruit & orange

(NOTE: Unfortunately, the deadline for replying to the following proposal has already passed. However, you may still send your comments while the new standards are being written.)

Dec. 31, 1974, was deadline for comments on Agriculture Dept.'s proposal to revise its standards for grades of the product known as "canned grapefruit & orange for salad."

Florida Cannery Association, which represents all processors of "canned grapefruit & orange for salad," asked Agriculture to revise the standards because of the similarity of this product to canned grapefruit. Canned grapefruit standards were revised Oct. 25, 1973, also at the request of the association. It said previous standards did not allow for problems caused by mechanized segmenting & filling operations.

Consumers could benefit to the extent that the machinery partially replaces the hand segmenting process. Mechanized segmenting might keep down costs—& retail prices—of the product.

Proposed changes would:

- Eliminate drained weight as a factor of quality. Agriculture says this would be consistent with other U.S. standards since drained weight is variable from can to can.
- Lower the minimum drained weight from 56¼% of the can's liquid capacity to 53%. This is 3% above Food & Drug Administration's (FDA) minimum fill of container. FDA has a mandatory standard for canned grapefruit of 50%. The 53% minimum would bring this product into con-

formity with Agriculture's voluntary canned grapefruit drained weight standards.

- Require that 65% (instead of the present 75%) of the fruit segments in a can be whole or almost whole. This change would compensate for unavoidable breakage resulting from mechanized operations. Segments used to be separated entirely by hand, assuring more whole segments—it is now done partly by hand & partly by machine.

- Permit loose floating particles of grapefruit & orange in the product.

- Permit the addition of orange juice to the product.

Grading under Federal standards is voluntary, but if the product is labeled with a Federal grade, it must meet Federal standards.

Details—*Federal Register*: Dec. 16, 1974, page 43551; Oct. 23, 1973, page 29210. CONSUMER REGISTER: Dec. 15, 1973. Send comments to Hearing Clerk, Agriculture Dept., Washington, DC 20250.

Bicycle safety (continued)

Feb. 6 is deadline for comments on Consumer Product Safety Commission's (CPSC) proposal to set a new effective date for mandatory safety requirements on all bicycles & to ban sale of bicycles that do not meet requirements.

CPSC also is proposing amendments—& seeking consumer comments on them—to the regulations it issued July 16, 1974, concerning (1) crank differential of bikes equipped with footbrakes, (2) handlebar stem-to-fork clamp test, (3) chain guards & (4) instructions & labeling. Amendments would become effective 120 days after CPSC acts on them & publishes them in *Federal Register*.

CPSC had previously set Jan. 1, 1975, as the effective date for requiring safety features in bicycles, but on Dec. 16, 1974, it granted a delay—at the request of bicycle manufacturers who said they could not meet the deadline.

Details—*Federal Register*: Jan. 7, page 1493; Dec. 16, 1974, page 43536; July 16, 1974, page 26100; May 10, 1973, page 12299. CONSUMER NEWS: Aug. 1, 1974. CONSUMER REGISTER: Jan. 1; Aug. 1, 1974; June 1, 1973. Send comments to Secretary, Consumer Product Safety Commission, Washington, DC 20207.

Vinyl chloride

On Dec. 30, 1974, Interior Dept. & Health, Education & Welfare Dept. (HEW) amended their regulations to provide end-of-service-life indicators on respiratory protective devices used by employees who are exposed to vinyl chloride. These indicators—stating date when devices lose their effectiveness—must appear on all devices the employees use after June 30. Devices are mandatory after Dec. 31, 1975. Until then, they are provided if the employees ask for them.

End-of-service-life indicators are necessary because vinyl chloride (which has been linked to liver cancer) is odorless & colorless.

Details—*Federal Register*: Dec. 30, 1974; Oct. 4, 1974, page 35890; May 24, 1974, page 18303; May 10, 1974, page 16896. CONSUMER REGISTER: Nov. 1, June 1 & June 15, 1974.

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Explosive Controversy

The Dispute Over PVC Sends Shock Waves Throughout Industry

By DANA L. THOMAS

DISCLOSURE last January of the death from angiosarcoma, a rare cancer of the liver, of three workers at B. F. Goodrich's polyvinyl chloride resin plant in Louisville prompted the U.S. Occupational Safety & Health Administration (OSHA) to take stiff measures to reduce the health hazard. After imposing temporary lower exposure levels for the chemical, OSHA ruled in October that, beginning next January 1, producers and fabricators must equip their plants to cut the level to near-zero — one-part per million — compared with the 50 parts per million previously in effect. Arguing that it is technologically and economically unfeasible to meet such a rigid standard, representatives of the industry have filed a suit seeking modification of the OSHA ruling; oral hearings will be held by the U.S. Court of Appeals this Friday. Meanwhile, the Society of the Plastics Industry has asked the court for an extension of its January deadline.

Needless to say, the polyvinyl case has sent shock waves throughout the industry. PVC resin is a basic material employed in a host of industrial and household products. Major uses include the packaging of food, the upholstery, wiring and component parts of autos, in building and piping, luggage and sporting goods. While producers employ 6,000 workers to turn out and fabricate the resin, two million jobs depend on its use. The value of products dependent on PVC runs over \$60 billion a year. In short, the OSHA ruling could have an adverse impact on a big slice of the U.S. economy.

"Blew Whistle on Itself"

Ironically, prior to the public announcement of the death of the Goodrich workers, the PVC industry itself did all the medical research which established the link between vinyl chloride and cancer. Ralph L. Harding Jr., president of the Society of the Plastics Industry, declares: "This is a unique situation. Industry financed the studies and blew the whistle on itself."

However, government agencies rushed in quickly thereafter, making up for lost time by imposing that industry spokesmen claim are unrealistic safety standards. The PVC issue is a test case and perhaps only the first in a long line of controversies ahead. For OSHA is just one of several new government agencies which have been established since 1970, as a result of the abbing of environmentalists, the rise of consumerism and the growing crusade for industrial health reforms.

The OSHA ruling on exposure levels already has had repercussions in the PVC business—including pressure on stock prices of major producers. Goodyear has announced it shutting down a facility at Niagara, slashing its output of PVC resin by 50%, or 50 million pounds, and eliminating 60 of the plant's 440 jobs. Goodrich, while programming a \$42 million outlay over the next three or four years to reduce worker expo-

sure, claims that even this huge investment will not enable it to meet OSHA's stringent requirements without resorting to respiratory equipment. The latter, it points out, not only could reduce worker productivity, but even more important, also pose a health hazard.

Severe Resin Shortages

Industry observers warn that if OSHA persists in its ruling, many more firms will be forced to shut down wholly or partially, creating a severe shortage of the resin and skyrocketing prices. On the other hand, government agencies, labor unions and lobbyists for industrial health controls argue that corporations must be held socially accountable and forced to put considerations of human life and safety above profits—whatever the cost. So the battle has been joined; the outcome, as noted, will have far-reaching effects.

Vinyl chloride, the basic raw material for polyvinyl resin production, is a gas at room temperature; it is synthesized from chlorine and ethylene in plants which resemble oil refineries. It was launched commer-

December, Dr. John Creech, a company doctor, learned that Earl Parks, who had begun working at the facility in 1943 and had been forced to retire in the late 'Sixties, owing to poor health, had died the previous August of a liver disease. Concerned about the suspiciously high number of Goodrich workers suffering liver diseases, Dr. Creech asked to see an autopsy on Parks. When he learned that Parks had died of angiosarcoma of the liver, the doctor recalled that two years before another Goodrich worker had succumbed to the same disease. Since angiosarcoma is exceedingly rare, the incidence of two such deaths in the plant's small workforce struck Dr. Creech as highly ominous.

He contacted Goodrich's occupational health director, who hired Tabershaw-Cooper Associates, an epidemiological research firm, to conduct an investigation of the mortality files of Goodrich workers. This had barely begun when a third worker, who had been at the Goodrich polyvinyl plant for 23 years, died of angiosarcoma. Greatly dis-

other blow. It was disclosed that an Italian Professor of Medicine, Cesare Maltoni, had discovered—two years before the announcement of the Goodrich deaths—in laboratory experiments that rats exposed to 250 parts per million of vinyl chloride developed angiosarcoma. The information had been transmitted to the government and medical societies in the U.S., but nothing had been done about it. Indeed, up until the Goodrich fatalities, OSHA continued to insist that it was safe for production plants to operate at a 500-ppm exposure level.

Another disclosure was equally sobering. Even before Professor Maltoni's discovery, Solvay & Cie, a Belgian polyvinyl maker, which became worried over the increasing incidence of acro-osteolysis among workers at its plants, hired Dr. P. L. Viola to do medical research on the subject. Dr. Viola was unable to develop acro-osteolysis in his laboratory animals, but he produced something worse — cancer of the liver.

Requested Secrecy

The results were reported in Tokyo in 1969, and in 1970, to the Tenth International Cancer Congress, meeting in Houston. To check out the results, four European chemical companies hired Professor Maltoni to conduct the aforementioned experiments. As noted, in 1972 he produced malignancies in animals which were exposed to 250 ppm of vinyl chloride. In January 1973, this information was passed on to the Manufacturing Chemists Association in the U.S., with the request it be kept confidential until Professor Maltoni had the chance to further analyze and interpret his studies. The ban was lifted in July 1973 and the report on Dr. Maltoni's experiments was transmitted by the Manufacturing Chemists Association to NIOSH and other government agencies.

Inexplicably, nothing was done about Professor Maltoni's findings. The Labor Department claims, in retrospect, that it didn't get the complete report; the MCA insists that the government did receive the data, but failed to comprehend its significance. In any event, Washington agencies made no effort to change the standards of exposure that OSHA had decreed for the industry in 1971—namely, 500 parts per million particles—double the level at which Dr. Maltoni produced liver cancer in his test animals. Meanwhile, Great Britain and Germany had tightened up their exposure levels. In the U.S., Dow Chemical had been raising its standards over the years, and Goodrich, whose subsequent announcement of fatalities was to touch off the storm, by the middle of 1973 had upgraded its exposure goal considerably above that of OSHA.

The disclosure that Washington and the MCA had known about the cancer-producing danger of vinyl chloride months before the Goodrich deaths sparked a public furor. A Nashville newspaper ran a series

Arguing that they are being asked to adhere to standards that are technically impossible and economically unfeasible, the PVC producers are taking their case to court.

cially in the 'Thirties and, thanks to its fire resistance and ability to be molded into a wide range of forms, was dubbed a "wonder plastic," which went into hundreds of industrial and household products. Last year, nine firms produced vinyl chloride gas in 14 plants. Their output was used by 21 companies to turn out over five billion pounds of polyvinyl resin, in 37 plants. The leading producer is B. F. Goodrich, followed by Firestone, Conoco, Union Carbide, Borden, Diamond Shamrock, Robintech, Tenneco, Air Products, Goodyear and Hooker (division of Occidental Petroleum).

Vinyl chloride had not been considered a seriously hazardous chemical. However, in the process of conversion from gas to resin, there is substantial leakage and the chief worry has been of plant explosions. The gas can induce narcosis (sleep). In fact, it was once tried out as an anesthetic but was discarded, since it caused heart irritation. During the 'Sixties, in cleaning out the vats during the conversion process, incidences of acro-osteolysis (bone and skin disease) cropped up among workers, and VCM processors introduced new techniques to reduce exposure. To further protect workers, OSHA, which was established in 1970 under the industrial health safety act, set limits of 500 parts per million of the chemical, to which workers could be exposed in gas and resin plants.

Matters were thought to be under control until the tragedies at the aforementioned Goodrich plant. Last

turbed, Goodrich management reported the deaths to officials of the National Institute for Occupational Safety & Health (NIOSH). After intensive consultation, the news was made public on January 22, 1974.

The announcement hit the industry like a bombshell. William Lloyd, director of health surveillance for NIOSH, declared, "This has to be one of the most startling findings ever in industrial medicine." Government health officials immediately launched a nationwide investigation. Staff members of NIOSH and OSHA went to polyvinyl chemical plants all over the country to study the situation. Charging that "workers are tired of being guinea pigs," officials of the United Rubber Workers and the Oil, Chemical & Atomic Energy Workers, demanded that PVC producers eliminate the exposure hazards or shut down.

Health Crusader

In addition, they asked Dr. Irving J. Selikoff, director of Mt. Sinai Hospital's Environmental Sciences Laboratory, to undertake medical investigations on their behalf. Over the years, Dr. Selikoff has built a reputation as a crusader for improved safety conditions in industry. A highly articulate spokesman, and a consultant to the AFL-CIO, the doctor is known as the Ralph Nader of the industrial health field. He pitched in vigorously. Assisted by labor personnel, he began digging into the health records at producers' plants.

Then the industry suffered an-

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Political Pressure

Needless to say, producers were shocked by the ruling. They thought that they had presented a strong case in pointing out that no animal—let alone human—death has been reported at under 50-ppm exposure. Some trade observers believe that the OSHA regulation was issued under heavy political pressure from unions and industrial health crusaders. Others feel that OSHA proposed the most severe standards possible, figuring that the industry would challenge the ruling in court and that the latter would then have the responsibility of resolving the issue.

Actually, OSHA wrote a loophole into its exposure regulation. This provides that while trying to get down to the one-part level with engineering modifications, the industry could meet the deadline by supplying workers with respiratory equipment. However, producers claim that such devices are in short supply. Even if they were plentiful, PVC makers contend that they are dangerous to use. At the OSHA hearings, government witnesses conceded that respirators, worn full time on the job, would be "instruments of torture." People with less than normal pulmonary functions can't breathe properly in them; 32% of the male population over 35 falls into this category.

Faced with the task of complying with a virtual zero-exposure level and a shortage of respirators, producers have warned that they may be forced to shut down all or a substantial part of their operations. SPI hired the Arthur D. Lit-

tle consultant firm to assess the impact on the U.S. of a total shutdown of VCM and PVC facilities. Surveying all the industries dependent on such materials, Little concluded that a complete shutdown would result in a loss of 1.5 million-2 million jobs and losses of at least \$60 billion in production and sales.

Serious Consequences

No one, of course, expects a total shutdown of the PVC industry—even if the OSHA

ruling is not delayed or modified by the courts. But just a partial shutdown or slowdown could have serious consequences. Hence, leading PVC makers are taking vigorous steps to try to adjust to the situation. Goodrich has announced that it will spend \$42 million over the next three or four years to reduce worker exposure to the lowest level possible in the six plants that make or process the resin.

Diamond Shamrock, a major resin maker with two new plants, already has reduced its exposure levels to a range of 5 to 25 ppm; it hopes to improve operations further with the use of respiratory equipment. The firm is going ahead with construction of a 200-million pound facility, which is expected to come on stream next year.

Robintech, a resin and polyvinyl pipe fabricator, says it plans to apply new engineering techniques in its Painesville, Ohio, plant, and a Japanese process it has acquired for a new plant in Texas. But for the industry as a whole, the future is filled with uncertainty.

DUAL-PURPOSE FUNDS

Friday, December 6, 1974

Following is a weekly listing of the unaudited net asset values of dual-purpose, closed-end investment funds' capital shares as reported by the companies as of Friday's close. Also shown is the closing listed market price or the dealer-to-dealer asked price of each fund's capital shares, with the percentage of difference.

	Cap. Shs.	N.A. Val	%
	Price	Cap. Shs.	Diff.
Am DualVest	3 1/4	3.47	- 9.9
Gemini	5	6.59	-24.1
Hemisphere	12	0.00	z
Income and Cap	3 1/4	3.31	- 5.6
Leverage	4 1/2	4.82	- 6.6
Pegasus Inco&Cap ..	4 1/2	-0.79	z
Putnam Duo Fund ..	2 1/4	2.22	+29.5
Scudder Duo-Vest ..	3 1/4	7.10	-33.8
Scudder D-V Exch ..	15	15.73	- 4.6

Lipper Analytical.

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BARRON'S

Tenneco Chemicals testified it might be forced to close its vinyl chloride plants if OSHA insisted on a zero level. The firm supported the industry's plan for a three-year program, but said it hoped to be able to achieve the final goal sooner in a new plant it is building in Texas.

Dr. Selikoff testified that, while the only prudent course was to provide a zero-level, if he were convinced the industry was making every effort to reduce exposure as fast as possible, he would be as "patient as Job" in requiring the ultimate standard. Peter Bommarito, president of the United Rubber Workers, argued that if PVC cannot be used safely, the industry ought to shut down. He observed that the country got along without the material for 200 years and could do so again if necessary.

Report Ignored

After the hearings concluded, OSHA, to help it arrive at a decision, contacted Foster D. Snell, a division of Booz, Allen, Hamilton, to undertake a study to determine what the consequences to the industry would be if standards were to be applied at various levels, ranging from zero exposure up to 50 ppm. In late August, Foster Snell reported its conclusions that it would not be technologically feasible to mandate a zero-level. It recommended that OSHA set gradually phased requirements for reaching its goal, to permit collection of additional data and fuller assessment of newer medical findings as they become available.

On October 4, OSHA published its ruling. Ignoring the Foster Snell report and the arguments presented by the industry at the hearings, it decreed that beginning January 1, 1975, the limit of exposure must be set at one part per million of VCM (or virtually a zero-level) as measured over an eight-hour working day, with a ceiling of 5 ppm measured over any period no longer than 15 minutes. To help achieve this standard, respirators will be required for all employees exposed to chemical inhalation in excess of these limits, except that until January 1, 1976, the use of such respirators will be discretionary for employees whose exposure is at a 25-ppm level or under. In addition, monitoring and measuring programs must be initiated in plants to determine whether exposure levels exceed 5 ppm; tests must be made monthly or quarterly.

Moreover, medical exams must be given every six months to workers who have had 10 or more years exposure at a plant, and annually to all others. Warning signs, posters and labels in plants must carry the inscription: "Cancer Suspect Agents"; they must be shown on all packages of PVC. Although the new ruling will apply to the producers of VCM and PVC and to the packaging, repackaging, transportation storage of the chemical, it won't include the handling or use of end products.

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EXPLOSIVE CONTROVERSY

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of articles, charging that a "Watergate-type cover-up" had been engineered to conceal the truth about the danger of the chemical and that the industry admitted the facts only when they were about to be discovered by the public. Dr. Selikoff, NIOSH and the unions demanded that VC producers reduce the exposure level to zero.

However, OSHA, which was responsible for taking into account the technical and economic consequences of its regulations, decided to compromise on a temporary emergency standard of 50 parts per million, pending further study. This level, the equivalent of a teaspoon of vinyl chloride in a room 20 by 20 feet, went into effect on April 5.

Then the government was embarrassed by another discovery. In mid-April, the Manufacturing Chemists Association, which had sponsored tests at the Industrial BioTest Laboratories in Northbrook, Ill., reported that two angiosarcomas had been produced in mice at the 50-ppm exposure level adopted by OSHA. That agency immediately proposed a change to a "non-detectable" level. But it decided before putting that standard into effect to hold public hearings to collect all available evidence.

Meanwhile, PVC producers, who had been keeping a low profile ever since announcement of the Goodrich deaths, were becoming alarmed at the adverse publicity and the threat of excessive Washington action. Industry spokesmen answered charges of labor and health groups that they were derelict in failing to act on the warnings of the European research by pointing out that these findings did not wave a red flag because all the liver cancers reported had occurred in animals. It wasn't until disclosure of the Goodrich deaths that it became apparent that the cancer could occur in human beings.

Makers of VCM and PVC agreed that they had an obligation to tighten safety standards. Via the Society of the Plastics Industry, they proposed as an alternative to zero-level exposures that they be permitted to reduce average levels over a three-year period to five ppm in VCM plants and 10 ppm in PVC ones. They also suggested an initial time-weighted average exposure of 25 ppm, with a ceiling level of 40 ppm, to be effective from October 5, 1974.

Meanwhile, throughout the country fabricators became worried that their business would be seriously affected, if producers were forced to shut down or curtail their supplies, owing to "unreasonable" government regulations. Fabricators bombarded the Labor Department with letters, warning of the hardships that would ensue from such action.

Spokesmen for the phonograph record business wrote that polyvinyl chloride is vital to their product and they couldn't survive if producers cut their supplies. A medical equipment manufacturer wrote that devices it provided for heart surgery and kidney dialysis treatment used PVC as a vital ingredient, and it could be forced to shut down if it couldn't get the resin.

Public Hearings

Amidst this tense atmosphere, OSHA opened its public hearings in Washington on June 25. They lasted through July 11, generating over 200 oral and written submissions, adding up to 4,000 pages of testimony. On the first day, Dr. Herman Kraybill, of the National

Cancer Institute, testified that OSHA's temporary standard of 50-ppm exposure was inadequate because at that level, according to recent studies, there was a high probability of causing cancer in man. On the other hand, Dr. Paul Kotin, former head of the National Institute of Environmental Health Services and a special consultant to Air Products & Chemicals Inc., argued it was inappropriate to set a standard for humans on the basis of animal experiments. Other representatives of Air Products said the firm had hopes of achieving an average time-weighted exposure of 20-25 ppm of VCM in their plants by October 1974. However, they stressed that it would be impossible to do better without significant improvements in current control technology.

A team from Dow Chemical testified that the firm had already gotten its level down 10 ppm, on an eight-hour time-weighted average, in most of its operations.

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