VRD 000200526

EPIDEMIOLOGICAL STUDY OF VINYL CHLORIDE WORKERS

Final Report - May 2, 1974

I. SUMMARY

Eight thousand three hundred and eighty four men who had had at least one year of occupational exposure to vinyl chloride before December 31, 1972, were followed in a historical prospective mortality study. The major findings of the study are:

1. The overall mortality of the study population was approximately 75 percent of what would be expected in a comparable population of U. S. males.
2. No cause of death showed a statistically significant excess over what would be expected in a comparable U. S. male population.
3. No new deaths identified as angiosarcoma of the liver were found.
4. All previously known Angiosarcoma deaths in the study population during the study period were found as part of the routine study procedure.
5. Cancers of the liver (primarily angiosarcoma), respiratory system, brain, and cancers of unknown primary site, as well as lymphosarcoma, occurred more often than expected in those members of the study population with the greatest exposure. Even though the excesses were not statistically significant, the findings warrant further study.
6. Other cancers occurred at lower levels than in the general male population, with the exception of cancers of the buccal cavity and pharynx. There was an excess of these

VRD 0002001527

cancers, which however was inversely related to exposure. The explanation for this finding is not apparent.

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

250 PARK AVENUE · NEW YORK, NEW YORK 10017 ·· 212/687-2675

CHEMICALS
RESEARCH
MAY 9 1974

VRD 0002007528

MEETING NOTICE

May 7, 1974

TO: MEMBERS OF THE VINYL MONOMERS &
PVC PRODUCERS AD HOC COMMITTEE

Dear Member:

At its May 3, 1974 meeting, the Steering Committee established an EPA Committee chaired by Warren Ferguson of Allied Chemical Corporation. Mr. Ferguson has summed up the problem we face by saying:

> "The OSHA requirements for vinyl chloride manufacture and use will in most cases require far higher standards of ventilation of work areas and of potential emission sources than has up to now been customary. It is reasonable to expect that EPA will establish emission standards designed to protect the general public from a newly recognized carcinogenic risk.
>
> "The current consensus of informal opinion seems to be that proven technology does not now exist for the removal of vinyl chloride from highly dilute air streams."

Therefore, there is a need for qualified individuals to meet to consider the technical options available to us. In order to review the problem and discuss these technical options available to us, a meeting will be held on Monday, May 20, 1974 at the Saddle Brook Marriot, Garden State Parkway at Interstate 80, Saddle Brook, New Jersey, beginning at 11:30 a.m. You should plan on spending the major portion of the day at the meeting.

Luncheon will be served, and following customary SPI practice, the attendees will be subsequently billed for their proportionate share of the meeting expenses.

Please complete and return the attached attendance indication form advising who your representative will be just as soon as possible so that suitable arrangements can be made.

VRD 0002007529

If you plan to stay at the Marriott please make your reservations directly with the hotel, mentioning you will be attending the SPI meeting.

We look forward to seeing you on May 20.

Cordially,

Thomas J. McGrath
Director of Packaging Services

TJM/mm
att.

VRD 0002087530

PLEASE COMPLETE AND RETURN TO:

Mr. Thomas J. McGrath,
Director of Packaging Services
The Society of the Plastics Industry, Inc.
250 Park Avenue
New York, New York 10017

I will [ ] will not [ ] attend the meeting of the EPA Committee of the Vinyl Monomers & PVC Producers Ad Hoc Committee on Monday, May 20, 1974 at the Saddle Brook Marriot, Garden State Parkway at Interstate 80, Saddle Brook, New Jersey, beginning at 11:30 a.m.

I do [ ] do not [ ] plan to stay for lunch.

NAME_____

COMPANY_____

ADDRESS_____

_____

VRD 0002001545

Vinyl Chloride and Cancer

By John Saar

The writer is a member of the Metropolitan staff of The Washington Post.

BEFORE IT WAS identified earlier this year as the carcinogenic killer of 12 industrial workers, vinyl chloride was accepted as a cheap and almost innocous gas with a varity of uses. Pressurized into consumer-sale aerosol cans, it served as the propellant for insecticides and hairsprays; as the base ingredient in a common plastic—polyvinyl chloride (PVC)—it is omnipresent of everyday life as bottles, pipes, wrapping, car upholstery, phonograph records and sundry other products.

With dramatic speed over these last few months, our understanding of the apparently compliant slave gas has been unpleasantly changed. Unmasked by an Italian research chemist, it now stands convicted in the deaths by a rare and invariably fatal liver cancer of the 12 plastics workers in the last 13 years.

Now—in the words of one researcher—it "casts a long shadow" over the lives of many thousands of workers in second-echelon, plastic-using industries. And if the lethal qualities of viynl chloride have been overlooked by the manufactureres, just how justified is the consumers' reliance on that most commonly used artificial material—plastic?

The already proven relationship between vinyl chloride and angiosarcoma—a liver cancer which generally kills an average of only 21 persons a year in the United States—is the latest of the chemical time bombs to threaten our industrial workers and, if the forebodings of some researchers are borne out, it may be worst.

That suspicion is under high priority investigation by at least seven governmental and medical research groups—an effort one involved expert in environmental health calls "unprecedented in both scope and intensity."

"Potent Carcinogen"

"VINYL CHLORIDE," added Dr. Irving Selikoff, a professor of medicine at the Mount Sinai School of Medicine, New York and director of the Environmental Sciences Laboratory there, "is a very potent carcinogen in the center of our great chemical process industry and a product used throughout society and industry."

Dr. Joseph A. Wagoner, working 15-hour days to direct another key investigation for the National Institute for Occupational Safety and Health (NIOSH), calls vinyl chloride "one of, if not the most potent carcinogens."

"The already proven relationship between vinyl chloride and angiosarcoma is the latest of the chemical time bombs to threaten our industrial workers."

With the dangers of vinyl chloride established in the grimmest fashion by death certificates, researches are pressing with unusual urgency for some answers to a whole spectrum of far-reaching question. They want to know exactly what the health risks are for approximately 6,500 people who work in 37 plants where vinyl chloride is polymerized into polyvinyl-chloride.

Beyond that, there is an urgent need to establish the hazerds, if any, for the tens of thousands of other workers who fashion the raw PVC into products and for the public at large which uses them.

Other agencies engaged in active research are the Natinal Institute for Environmental Health, the Environmental Protection Agency, the National Cancer Institute, Environmental Protection Administration for the City of New York and the Center for Disease Control, Atlanta.

The investigations are far from complete, but under the gun of a continuing health hazard of uncertain proportions, scientists will discuss their interim findings at an international conference May 10 organized by the New York Academy of Sciences.

That link is now just about as certain as the relationship between the tubercle bacillus and the etiology of tuberculosis, according to Sellikoff: "I don't think there's any doubt of a firm, strong association between angiosarcoma and vinyl chloride exposure," he said.

Problems Found

EXPERTS HERE expect reports from American and European scientist to further substantiate the link between vinyl chloride and angiosarcoma and to predict a potential death exposed workers.

Two months ago, Dr. Selikoff took a 50-strong team of medical personnel to the Niagara Falls, N.Y., plant where 400 men make polyvinyl chloride for Goodyear. He is unwilling yet to detail results of the mass clinical screening conducted there, but commented: "We have found problems there. We have found vinyl chloride-associated disease."

The vinyl chloride hazard has been exposed at a quickening pace over the last few months as animal researchers found that mice and rats dosed with the chemical developed angiosarcoma and medical researchers found evidence of the same rare tumor among plastics workers.

As the evidence hardened, government agencies have drastically changed legislation regarding vinyl chloride. Some of the pressure for changes stemmed from the alarming results of internal research programs. More in the form of petitions, dozens of phone calls and disclosure actions came from the feisty goading of a Ralph Nader-funded Health Research Group (HRG).

In mid-January, B.F. Goodrich announced the death of three long-term employees at the Louisville polyvinyl chloride plant with the significant addendum that the company was investigating whether the deaths "were related to occupational causes."

Since then, 94 consumer products containing vinyl chloride have been either voluntarily withdrawn by manufacturers or banned from sale by the EPA and FDA. These included 41 aerosol pesticides for household use, 26 home and professional hairsprays, 13 deodorants and anti-perspirants.

The radical change in attitude toward the colorless gas is reflected in Department of Labor regulations on the exposure of industrial workers. Previous regulations limiting workers to 500 parts per million were based on avoiding combustible concentrations and toxic levels sufficient to cause dizziness and nausea. A new emergency standard limiting exposure to 50 parts per million is now in force and the Occupational and Safety Health Administration (OSHA) plans to seek a permanent standard of no measurable level.

IRRD 000200754

Though their studies are incomplete, the researchers are sure enough about vinyl chloride to express a uniform consternation the idea of workers being exposed to levels as relatively low as 50 ppm. "I don't think it's adequate," said Selikoff. "It would be foolhardy to say this lower level is safe. If cancer occurs at higher levels, it will occur at lower levels, though less frequently."

'It's Heartbreaking!'

THE PERCEPTION of vinyl chloride as dangerous in *any* amount leads to a depressing comparison with the levels accepted as reasonable by the chemical industry as late as January this year. Vinyl chloride readings declared by the companies themselves ranged in ordinary production from 20-100 ppm. But occasional very high readings were admitted. The plastics division of Uniroyal at Painesville, Ohio, for instance, told NIOSH researchers that workers scaling the vessels in which PVC is made were briefly exposed to levels as high as 1,600 ppm. When told that, Selikoff exclaimed, "It's heartbreaking!"

With responsibility for governing vinyl chloride use falling between the overlapping jurisdictions of several federal agencies — all adjusting at differing speeds to new knowledge on the gas — some important gaps still exist.

Vinyl chloride production is estimated at 7 billion pounds a year and it is still being transported by rail and highway under dangerously outdated hazard rules. On April 14 a freight train derailed and dumped a tank car of vinyl chloride on a Philadelphia expressway. Dr. Wagoner broke from his work in Cincinnati to place telephone calls to the Pennsylvania Poison Center and the Penn Central Railway. Neither knew they were dealing with a proven cancer-causing agent. In the past three years, eight spillage incidents have been reported.

The Health Research Group, partially responsible for persuading the EPA to ban sales of inside insecticides, is now pushing the agency to seize all outdoor vinyl chloride aerosols with the logical argument that on present knowledge any further consumer exposure is intolerable.

Emergency Revision

THE RECENT history of vinyl chloride shows a fascinating helter-skelter pattern of scientific initiative and governmental response as society staged a hurried retreat from a chemical regarded as relatively benign since it was first manufactured in 1939.

• Jan. 20, Dr. Joseph A. Wagoner director of NIOSH's field investigation division begins, with "a sense of national urgency," an epidemiological study of four long-established PVC manufacturing plants. At this time the research is going full-force, occupying 18 out of 32 people on his staff. One branch has shut down work on every other project to handle the vinyl chloride emergency.

• In mid-February, Italian scientist Prof. Cesare Maltoni told a hurriedly assembled OSHA aring that two out of 67 rats subjected to daily dosages of vinyl chloride developed angiosarcomas. At a very high level of 6,000 parts per million, 11 out of 72 rats developed the rare tumors. However, the bombs in Maltoni's findings that led to an immediate emergency revision of the industrial atmospheric levels then standing at 500 ppm was the statement that some rats developed the tumors at 250 ppm.

• Feb. 14, EPA forms a task force under Glenn Schweitzer to assess overall health and environmental risks associated with vinyl chloride and PVC. On April 10, he directs EPA's 10 regional offices to test the water, air and solid waste emissions from at least one plant using vinyl chloride to make PVC.

• Feb. 21, the HRG petitioned the FDA to ban and name cosmetics employing vinyl chloride as a propellant on the basis of "well-documented carcinogenicity." A similar petition went to EPA Administrator Russell Train, calling for suspension of vinyl chloride products regulated by the EPA.

• March 23. Responding to the HRG petition on pesticides, the EPA states they have no listing of products containing vinyl chloride and are sending a warning letter to all 35,000 pesticide manufacturers suggesting the substitution of another gas.

• March 26, The Health Research Group — unsuccessful in persuading Clairol to withdraw vinyl chloride-powered hairsprays from the market—takes the dispute to the FDA in a letter to the administrator Dr. Alexander N. Schmidt. The substance of the HRG's case was Clairol's admission that users of the sprays were exposed to 200 ppm for a one-minute duration. The HRG director, Dr. Sidney M. Wolfe, reproved the FDA: "Whereas this inaction by the FDA must be welcome and financially beneficial to Bristol-Myers and its Clairol subsidiary, it may be fatal for many unsuspecting citizens of this country."

• April 3. The FDA announces action to end the use of vinyl chloride in products under its control. The order concerns three manufacturers and about 50 products. Calling the hazard to hair-spray users "extremely remote," Clairol Inc. nevertheless announces the recall of 100,000 cans of Summer Blonde and Miss Clairol aerosol hair sprays.

• April 5, In response to a March 11 recommendation from NIOSH that the acceptable industrial level should be zero, the Department of Labor announces an interim emergency level of 50 ppm.

• April 17. The EPA identifies 20 products containing vinyl chloride, leaves 21 more unnamed pending manufacturers' approval of their publication.

• April 19, EPA administrator Russell Train hears the result of some crucial experimentation by his own people. Under test, pesticides on public sale raised the vinyl chloride concentration in a small room such as a bathroom to 400 ppm in a 30-second burst. Without light or ventilation, the researchers reported to their chief, the concentration of gas diminished by only 1 per cent in a four-day period.

• April 24, Citing those tests and the easy availability of substitute gases, Train signs an order banning all vinyl chloride products for indoor uses. The EPA administrator was doubtless also aware of some preliminary findings in a long-term study by the Manufacturing Chemists Association which disclosed tumors in mice at levels of only 50 ppm. The names of seven of the vinyl chloride products regulated by the EPA still have not been released.

Gloomy Prediction

THE POSSIBLE significance of the 12 deaths currently associated with vinyl chloride-induced angiosarcoma for the 6,500 work force drew a gloomy prognostication from Dr. Selikoff: "Twelve deaths may not sound many, but put it in this perspective. In the early 1950s there were maybe 1,000 workers in PVC plants. In the normal course of events something like 100-150 would have died. Twelve deaths out of 100-150 suggests a rate of 12 per cent."

Selikoff's study of Goodyear's vinyl chloride operation included a trace on 98 per cent of all employes with five or more years service. To the company's discovery of one angiosarcoma death, Selikoff's workers added the names of two others whose causes of death were misdiagnosed on death certificates. Researchers interviewed family doctors and hospital pathology departments and studied original pathology slides to verify the true cause of death as angiosarcoma.

Misdiagnosis owing to the rarity of the particular strain of cancer is also troubling Wagoner's NIOSH researchers: "Out of the 12 deaths so far confirmed, 33 per cent were misdiagnosed. One was classified as cirrhosis and another as a benign liver tumor." (The National Cancer Institute has taken the unprecedented action of opening a national registry of all angiosarcoma cases.)

Though Wagoner's primary concern is with the safety of industrial workers, the three questions he is trying to answer encompass far broader ramifications.

"We want to assess the magnitude of the risk — how many other cases are there? And secondly, whether other organs of the body are affected by vinyl chloride. I would suspect we should be looking at the lung as a target organ."

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Wagoner's third area of investigation is the potential vulnerability of other industrial workers, and finally, the consumer. "We want to know how widespread exposure to vinyl chloride is in the making of PVC and in the variety of uses of PVC."

Casting the Net Wide

SO FAR, Wagoner's "walk-through" survey teams of doctors, engineers, biostatisticians and epidemiologists have studied and microfilmed personnel records at four plants. They have examined conditions under which vinyl chloride has been used and the likely exposure by leakage of the workers.

But the prime objective is a comprehensive study of mortality among workers at the plants. From a search of the microfilmed personnel records, the NIOSH researchers are establishing how many of the plants' past and present employees are dead, and what they died from. The net is cast wide to examine all fatalities because the Goodrich Company's own screening program at the Louisville plant disclosed 20 cases of liver abnormalities in addition to previously undiagnosed angiosarcoma in two workers.

From the autopsies of former workers who died in non-related accidents, the researchers hope to understand the range of conditions vinyl chloride may produce other than liver malignancy.

Cooperation by all peripherally involved in the NIOSH study has been excellent, Wagoner says. The Ohio State motor vehicle registry which is able to provide an initial check on whether former employes of an Ohio plant are alive has cut the response time from three months to three hours, and police scout cars have been offered to ferry materials.

The pressure is constant. "Everyone wants results," says Wagoner. "We are looking for long-term carcinogenic results, but at the moment we have more questions than answers."

When properly cured and aged, finished PVC is thought no to exude vinyl chloride fumes. This belief is being tested by NIOSH in experiments involving the placing of PVC pellets in closed chambers and measurement with sensitive devices. The extent of consumer hazard will depend on the as yet unknown frequency with which vinyl chloride "leaches" out of a host of everyday products.

NIOSH is now placing a contract for the full investigation of "leaching." Wagoner will say only, "We don't know what the full spectrum of disease is but there are concerns for the consumer."

At the National Cancer Institute where another major vinyl chloride search program is under way, and an angiosarcoma patient is undergoing chemotherapy and study Dr. Umberto Saffiotti associate director of carcinogenesis, considers the gas "a major potential hazard," and "a serious problem for consumers."

While the exposure of an individual consumer is lower than a vinyl chloride worker, an infinitely greater number of people are involved, he points out: "There may be millions of people involved and an incidence at a much lower rate in a large population may still be a substantial number of cancer cases."

HRG director Wolfe sees the known angiosarcoma deaths as the start of a series of cases and the best reason for reducing consumer exposure to vinyl chloride immediately.

"We are now seeing people who got really high doses. In the next few years we may see beauticians exposed to doses not quite so high through hair sprays. A very few years later we may see consumers who just happened to be heavy aerosol users."

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MAY 2, 1974 11:09 AM

F. KENNEDY PONCA

REGARDING WAYNE SORENSON'S DRAFT LETTER TO MCCOWIN OF FDA SENT TO KLS. I WOULD LIKE TO DISCUSS IT WITH YOU BEFORE WE SEND ANYTHING. THE ANALYTICAL PROCEDURES SECTION SEEMS COMPLETE AND WELL ORGANIZED BUT THE INITIAL DATA WE HAVE GENERATED APPEARS TO BE RANDOM AND INCOMPLETE IN EXPERIMENT SCOPE AND ASSOCIATED DATA ON TEST CONDITIONS. IS THIS INITIAL DATA OF SUFFICIENT SCIENTIFIC QUALITY TO REPORT TO OUR MANAGEMENT OR THE FDA. WHEN WILL MORE COMPLETE RESULTS BE AVAILABLE OF THE TYPE WE ARE SEEKING. GIVE ME A CALL.

J. J. LANGFORD AF

END

CHEMICALS RESEARCH
MAY 2 1974
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cc: √E. Kenna
L. Nelson
K. Hunter

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PARK EIGHTY PLAZA EAST
SADDLE BROOK, N. J.

SMITH OF ROBINTECH AND I HAVE BEEN CHARGED BY OSHA SUBCOMMITTE, VCM/PVC AD HOC COMMITTEE OF SPIT WITH PREPARATION OF POSITION PAPER ON THE EFFECT OF ANY PROPOSED PERMANENT VCM EXPOSURE STANDARD ON
PVC PROCESSORS. TO COMPLETE THIS TASK WITHIN TWO WEEKS, WE URGENTLY REQUIRE THE RESULTS OF ANY VCM LEVEL MEASUREMENTS IN PROCESSING PLANTS, DESCRIBING LOCATIONS WHERE MEASUREMENTS TAKEN AND METHODOLOGY EMPLOYED.

PLEASE FORWARD TO ME ANY AVAILABLE DATA AS SOON AS POSSIBLE.
JACK JAGLOM
THE PANTASOTE CO. OF N.Y., INC.
26 JEFFERSON ST.
PASSAIC, N. J. 07055
TELEPHONE: 201-777-8500
TWX: 710-989-7108
NNNN

WRS -
Flynt asked would you please gather information for him & review.
Thanks

CHEMICALS RESEARCH
MAY 7 1974

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M

The National Association of Food Chains

1725 Eye Street
Northwest
Washington, D.C.
20006
Telephone:
(202) 331-7822

VRD 000201554

April 29, 1974

Mr. Jerome Heckman
Keller and Heckman
1150 17th Street, N.W.
Washington, D. C. 20036

Dear Jerry:

To date we have met with Dr. Virgil O. Wodicka (Director, Bureau of Foods, FDA), Richard J. Ronk (Director, Division of Food and Color Additives, FDA), and Richard E. Feltner (Assistant Secretary for Marketing and Consumer Services, USDA) regarding the impact that a disruption of the supply of PVC might have on the food industry.

It would be most helpful for us if you could ask one of SPI's experts to compile a list for us of all the uses of VC or PVC that might be found in a supermarket. We are contemplating having a number of meetings with government officials in the near future and a prompt response would be appreciated.

Best wishes.

Sincerely,

Paul A. Korody, Jr.
Director of Governmental Affairs

PAK:blm

VAU 0001001559

interim 2.0 grams per mile NO_x standard established by the July 30, 1973, decision.

On December 28, 1973, the Administrator announced receipt of several additional requests for suspension of the 1976 NO_x standard, and delineated procedures for disposition of those applications and all other applications for suspension filed with the Administrator prior to January 4, 1974 (see 38 FR 35528). Then on February 1, 1974 (see 39 FR 4132), the Administrator granted suspension of the 1976 NO_x emission standard to sixteen (16) additional manufacturers.

On March 25, 1974, the Administrator announced receipt of two additional requests for suspension of the 1976 NO_x standard (Automobiles Peugeot and Isuzu Motors), and delineated procedures for disposition of those applications and all other applications for suspension filed with the Administrator prior to April 5, 1974 (see 39 FR 11133). Subsequent applications for suspension have been filed by Checker Motors Corporation (received March 1, 1974), Mitsubishi Motors Corporation (received April 1, 1974), Toyo Kogyo Company, Limited (received April 3, 1974), SS Automobiles Incorporated (received April 5, 1974), Toyota Motor Company, Limited (received April 5, 1974), and Avanti Motor Corporation (received April 5, 1974).

In accordance with the procedures outlined in the March 25, 1974, FEDERAL REGISTER notice, each application was made available for public review and comment. Since no public comments were received on the submitted applications, I have determined that no useful purpose would be served by holding a suspension hearing on these applications.

On the basis of our review of the submitted applications, I have determined that each applicant has made all good faith efforts to meet the 1976 NO_x statutory standard. Accordingly, I hereby grant suspension of the 1976 NO_x standard to each of the eight (8) applicants set forth above. Each applicant's 1976 model year light duty vehicles sold in the United States will be required to meet the interim NO_x standard of 2.0 grams per mile.

Dated: April 19, 1974.

JOHN QUARLES,
Acting Administrator.

[FR Doc.74-9614 Filed 4-25-74;8:45 am]

TECHNICAL ADVISORY GROUP TO THE MUNICIPAL CONSTRUCTON DIVISION

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that a meeting of the Technical Advisory Group to the Municipal Construction Division will be held at 9 a.m. on May 13 and 14, 1974, at the Dallas Regional Office, 1600 Patterson Street, Dallas, Texas.

The purpose of the meeting is to review and discuss the following subject matter: Section 937 and Value Analysis, Non-restrictive specifications, reactions to current title II regulations, Best Practicable Treatment Technology, Design/Construct, and section 208 regulations.

The meeting will be open to the public. Any member of the public wishing to attend should contact the Executive Secretary, Mr. Harold P. Cahill, Jr., Director, Municipal Construction Division, Environmental Protection Agency, Washington, D.C. 20460. The telephone number is area code 202-426-8986.

ROGER STRELOW,
Acting Assistant Administrator for Air and Water Programs.

APRIL 19, 1974.

[FR Doc.74-9511 Filed 4-25-74;8:45 am]

VINYL CHLORIDE

Emergency Suspension Order Concerning Registrations for Certain Products and Intent to Cancel Registrations

Notice is hereby given of the emergency suspension of, and notice of intent to cancel the registrations, under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"; 7 U.S.C. 135 et seq., 7 U.S.C. 136 et seq.), of all pesticide spray products containing vinyl chloride, whether as an active or inert ingredient, for uses in the home, food handling establishments, hospitals or in enclosed areas. Concurrent with this notice of suspension and notice of intent to cancel, the Environmental Protection Agency, is requesting that all existent stock of such products be recalled by the manufacturers.

FINDINGS OF FACT

1. In January 1974, it was reported that four workers who had had intimate occupational contact with vinyl chloride had died from angiosarcoma of the liver.

2. Angiosarcoma of the liver is an extremely rare form of cancer. Data from the Third National Cancer Survey, conducted by the National Cancer Institute over the three-year period, 1969 to 1971, indicates that the number of cases of angiosarcoma of the liver expected in any one year could range from 11 to 53 for the total United States population.

3. On February 15, 1974, an Italian scientist, Professor Cesare Maltoni of the Bologna Institute of Oncology, reported on an experiment in which rats exposed to vinyl chloride gas for four hours per day, five days per week, for 127 weeks developed angiosarcoma of the liver. These cancers were found at an increasing frequency at several dosages, beginning at 250 ppm and above, but not at 50 ppm, the lowest dosage tested.

4. Since the first occupational reports this year, several more cases of angiosarcoma of the liver have been confirmed, bringing the total number of these cancers among occupationally exposed workers in the United States to twelve. Two additional deaths from angiosarcoma have been reported among occupationally exposed workers outside of the United States. The evidence relating vinyl chloride exposure and these deaths is circumstantial, but strongly suggestive of a causal relationship, especially when combined with animal data.

5. In 1973, the Manufacturing Chemists Association contracted with Industrial Bio-Test Laboratories, Inc. of Northbrook, Illinois, to conduct laboratory studies exposing mice and hamsters as well as rats to vinyl chloride gas. While this experiment is not yet completed, there have been a high number of deaths among the test animals, controls as well as exposed. In the course of examining these animals to determine the cause of death, a significant number of the dead mice in the exposed group showed tumors of various sorts. Two cases of angiosarcoma of the liver were observed in mice exposed to 50 ppm vinyl chloride in the air, four cases of the rare cancer in mice exposed to 200 ppm, and in seventeen of those exposed to 2,500 ppm. No angiosarcomas have been found in the rats or hamsters that have died during the course of the experiment. The significance of these figures is still not fully understood because data on the deaths in the control group of mice has not yet been fully analyzed. Nevertheless, the observation of a dosage-related pattern of occurrence of this rare form of cancer, coupled with the previous results in Italy, provides strong evidence that exposure to vinyl chloride can cause liver cancer.

6. Seventeen manufacturers have registered pesticidal aerosols in which vinyl chloride was one of the inert ingredients, and thus unlisted on the label. These manufacturers plus their distributors account for 41 different brand name products. Vinyl chloride is used as a propellant component in such aerosols.

7. Although all of these mnufacturers state that they have stopped using vinyl chloride as a propellant, some as early as May 1973, there are at least an estimated 19,000 cans of such products in commercial channels.

8. Last Friday, I learned of preliminary testing and calculations done by EPA involving the use of an aerosol containing vinyl chloride showing that a 30 second release of the aerosol could result in a concentration as high as 400 ppm in the air. In a separate test, preliminary results showed that after as long as four days, only about 1% of the vinyl chloride gas would dissipate under conditions where the exposure area was not ventilated and little, if any, light was present. Calculations based on this information, assuming three changes of air per hour in an enclosed area, and experiments by EPA scientists measuring vinyl chloride levels following spraying in the home would indicate that a detectable concentration of vinyl chloride could still persist for several hours after spraying.

9. Exposure to vinyl chloride has been associated with a significant number of cases of a rare liver cancer in experimental rats and mice, and in humans. Although vinyl chloride is apparently no

longer being used as a propellant in pesticides, some stocks remain on the market. The use of these pesticides in an enclosed space, even in short bursts (e.g., 30 seconds), could result in exposure levels similar to those which have produced angiosarcomas in test animals. The health implications for humans at these levels for short exposure periods are undetermined, but it is prudent to assume that any exposure at these levels will have increased the risk of cancer should the strongly suspected causal relationship between vinyl chloride and cancer be finally confirmed.

10. The benefits of the use of vinyl chloride as a propellant are very small because several suitable substitutes exist which, in fact, are frequently used. Although the number of pesticide products containing vinyl chloride presently in commercial channels or in use is not thought to be substantial, the risk of continuing such use in the face of acceptable substitutes is unjustified.

11. Attached to this order are the names of the pesticide products containing vinyl chloride which are known by this Agency to be registered for uses in the home, food handling establishments, hospitals or in enclosed areas. There may be others.

Conclusions

Section 6(c) of FIFRA provides for the suspension of a registration of a pesticide if the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation proceedings under section 6. Section 6(c) also provides for issuance of an emergency order of suspension by the Administrator in the event he finds that an emergency exists that does not permit the holding of an expedited hearing on the question of suspension before issuing an order. The statute also provides a general definition of the term "imminent hazard" in section 2(l) which states that "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation would be likely to result in unreasonable adverse effects on the environment. A determination of unreasonable adverse effects on the environment must consider the degree of risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide (Section 2(bb)).

The evidence available at this time indicates the presence of a clear risk to human health from continued exposure to vinyl chloride. Indeed, this chemical presents a most unusual case because the rare form of cancer found in occupational workers can be readily demonstrated in test animals. Thus we are faced with a substantial risk to human health upon continued exposure to vinyl chloride. The existence of this risk would require a compelling demonstration of benefits to justify the continued use of the product pending the outcome of either cancellation proceedings or any hearing pursuant to section 6(c)(2) of FIFRA.

Present information indicates that most, if not all manufacturers of pesticides containing vinyl chlorides as a propellant, are willing to utilize substitute substances for this purpose. The Environmental Protection Agency has already received several applications for amended registrations to eliminate vinyl chloride as an ingredient. It is my understanding that similar amendment applications will be forthcoming from other manufacturers. Thus, there is no indication that elimination of use of these products pending completion of suspension and cancellation proceedings will have any effects upon availability of the associated aerosol pesticides. Indeed, in the course of investigating use of these products prior to this order, instances were discovered of previous voluntary discontinuance of the use of vinyl chloride as a propellant (without amended registrations having been submitted or issued).

Although voluntary discontinuance of the use of the substance is a commendable development, significant quantities of pesticide products containing vinyl chloride have previously been distributed and are now in retail outlets or in actual use. In addition, although the Environmental Protection Agency desires, whenever possible, to secure voluntary compliance rather than proceeding by order, the time required to insure that such compliance has actually taken place would necessarily delay achieving the most rapid possible nationwide cessation of the sale of products containing vinyl chloride, and the recall of existing stocks. Therefore, I have concluded that in view of the substantial risk from continued use of vinyl chloride, and the absence of any significant benefit from its continued use pending completion of cancellation proceedings pursuant to section 6, an imminent hazard does exist under the terms of section 6(c) of FIFRA and an emergency does exist which does not permit delay of suspension pending a possible hearing pursuant to section 6(c)(2) prior to issuance of an order of suspension. Indeed, I find that as a result of the above findings of fact, particularly the recent results of Agency testing, that immediate action is required.

Emergency Suspension Order and Notice of Intent to Cancel

In accordance with the attached findings and conclusions, it is hereby ordered that the registrations for all pesticide products containing vinyl chloride, whether as an active or inert ingredient, be suspended immediately for all uses in the home, food handling establishments, hospitals, or in enclosed areas. I also serve notice of my intent to cancel such registration within 30 days from the receipt of this notice by the registrant, or publication of this order in the Federal Register (April 26, 1974), which ever occurs later, unless the registrant makes the necessary corrections to its registration. These pesticide products containing vinyl chloride may not be legally shipped in interstate commerce.

Dated: April 24, 1974.

Russell E. Train,
Administrator.

Indoor Aerosol Pesticides Affected by Today's Suspension

Product	*Company*
Brulin Bug Bomb	Brulin & Co.
Paracide with Sevin	Carson Chemicals, Inc.
Demert Raw Roach, Ant and Wasp Killer.	Demert & Daugherty.
Cobra International Roach, Ant and Wasp Killer.	Cobra International [D].
Rexall Ant and Roach Killer.	Rexall Drug Co. [D].
Walgreen Ant & Roach Killer.	Walgreen Laboratories, Inc. [D].
Flea Killer for Dogs and Cats.	Chase Products Co.
Barcolene Spray Disinfectant.	The Barcolene Co.
Coop Dairy Insecticide for Milk Houses and Animals.	Farmland Industries, Inc.
Excelcide 16-oz. Aerosol Bomb.	The Huge Co.
Navy Brand Thrifty 50	Navy Brand Mfg. Co. [D].
Mothrid Moth Proofer	Hysan Corp.
Mothrid Moth Proofer Cedar Scented or Activated Moth Proof Spray Cedarized.	Liberty Products Co. [D].
Nokout 25 Aerosol Insecticide.	Hysan Corp.
Strike—Wasp and Hornet.	Albert Woods Wholesale [D].
Nokout 35 Insecticide.	Hysan Corp.
Spritz Metered Air Sanitizer.	Hysan Corp.
Anchor Flea, Lice and Tick Bomb.	Philips-Roxane, Inc.
F-L-T Bomb	Bio-Ceutic Laboratories [D].
WAYNE, Flea, Lice and Tick.	Allied Mills, Inc. [D].
Rodgers' Insecticide and Repellent.	Jay Rodgers Co.
Total Release Insect Fogger.	Spray-Chem Corp.
Crown "Total" Complete Release Insect Fogger.	Crown Chemicals, Inc. [D]
Roberts' "Total" Complete Release Insect Fogger.	Roberts Laboratories [D]
Chaperone Flea & Tick Killer.	Sudbury Laboratory
Pyrethrin Insecticide Pressurized Dairy Insecticide.	Woodbury Chemical Co.
COOP Pyrethrin Insecticide Pressurized Dairy Insecticide.	Farmland Industries, Inc. [D]
Mid-Am Brand Pyrethrin Insecticide Pressurized Dairy Insecticide.	Mid-American Dairymen, Inc. [D]

[D]—Distributor of Product Listed Above

[FR Doc.74-9719 Filed 4-25-74;8:45 am]

VRD 0002007569

VRD 000200761

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1999]

STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE

Notice of Intent To Prepare an Environmental Impact Statement

The National Environmental Policy Act of 1969 (42 U.S.C. section 102) requires each Federal agency to consider the environmental effects of proposed actions and to prepare environmental impact statements on major actions affecting the quality of the human environment. Accordingly, the Occupational Safety and Health Administration, U.S. Department of Labor, in conformance with its procedures for environmental impact statements (29 CFR Part 1999), announces its intention to prepare an environmental statement assessing the impact of a proposed standard for occupational exposure to vinyl chloride to be published in the FEDERAL REGISTER in the near future.

The Office of Standards Development, Occupational Safety and Health Administration, is currently collecting information and data on possible environmental impacts of the proposed standard, such as any adverse environmental effects which cannot be avoided should the standard be adopted; alternatives to such a standard; the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and any irreversible commitments of resources which would be involved if the standard be implemented. Those issues of particular interest are:

a. Any medical or toxicological evidence which indicates that exposure to vinyl chloride or its polymers produces adverse effects to living organisms, especially primates.

b. Current and historical levels of occupational exposure.

c. Combustible characteristics associated with vinyl chloride or its polymers, especially information correlating accident experience; damage to facilities, interruption of plant activities, and/or storage and shipment difficulties.

d. Identification of the uses of vinyl chloride or its polymers, through finished products, and determination of the quantity of use.

e. Any information suggesting substitutes for vinyl chloride or its polymers, to include estimates of the extent to which substitution is feasible.

f. Any suggested actions which will control the health hazards associated with production, storage, or shipment of vinyl chloride or its polymers through finished products.

g. Any other pertinent information.

Any person having information or data on this subject which is not readily available in the open literature is invited to submit it, with accompanying documentation, to the Director, Office of Standards Development, Occupational Safety and Health Administration, 1726 M Street, NW, Room 500, Washington, D.C. 20210 by May 17, 1974. All information received will be available for public inspection at the Office of Standards Development.

When the draft environmental impact statement on vinyl chloride is completed, copies will be available to any member of the public who requests it. A 45-day period will be allowed for the public to submit their comments.

Signed at Washington, D.C., this 18th day of April 1974.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.74-9300 Filed 4-23-74;8:45 am]

Wage and Hour Division

[29 CFR Part 511]

WAGE ORDER PROCEDURE FOR PUERTO RICO, THE VIRGIN ISLANDS, AND AMERICAN SAMOA

Changes in Procedures as the Result of the Fair Labor Amendments of 1974

Under authority provided in the Fair Labor Standards Act of 1938 (52 Stat. 1062, 1064, as amended; 29 U.S.C. 205, 206, 208) and Reorganization Plan No. 6 of 1950 (3 CFR 1949–53 Comp., p. 1004) and Secretary's Orders Nos. 13–71 and 15–71 (39 FR 8755 and 8756), it is hereby proposed to revise 29 CFR Part 511 to adapt the procedures set forth therein to the Fair Labor Standards Amendments of 1974, Pub. L. No. 93–259.

The proposed revisions of §§ 511.10 and 511.13 would prescribe the greater responsibility of the employers or of the industry in establishing its inability to pay the rates comparable to the ones in the various States. The amendment to § 511.8 would show the current title of the Director of the Caribbean Office.

Interested persons may submit written data, views, and arguments concerning the proposed revision on or before May 9, 1974. Such submissions may be filed with the Administrator, Wage and Hour Division, U.S. Department of Labor, 14th Street and Constitution Avenue, NW, Washington, D.C. 20210.

1. As amended paragraph (b) of § 511.8 would read as follows:

§ 511.8 Prehearing statements.

* * * * *

(b) Any interested person who wishes to participate on his own behalf or by counsel shall file a written prehearing statement. Not later than ten days before the first hearing date set for any committee in a notice of hearing concerning minimum wages for Puerto Rico or the Virgin Islands, or such other period of time as may be prescribed in a notice of hearing, or other notice published in the FEDERAL REGISTER, the original and 11 copies of the prehearing statement shall be filed at the Office of the Director of the Caribbean Office of the Wage and Hour Division, United States Department of Labor, 7th Floor, Condominio San Alberto Building, 1200 Ponce de Leon Avenue, Santurce, Puerto Rico, and one copy at the Office of the Administrator of the Wage and Hour Division, United States Department of Labor, Washington, D.C. 20210. If such statements are sent by air mail from Puerto Rico or the Virgin Islands to the mainland, or from the mainland to Washington, such filing shall be deemed timely if postmarked within the time provided. The number of copies of such statements and the time and places for filing them will be specified in notices of hearings to determine minimum wages for American Samoa. The prehearing statement shall describe the person's interest in the proceeding and shall contain (1) the prepared statement he proposes to give, if any; (2) a statement of the individual classifications and minimum wage rates, if any, he proposes to support; (3) the written data he proposes to introduce in evidence, including all tangible objective data to be submitted pursuant to § 511.13; (4) the names and addresses of the witnesses he proposes to call and a summary of the evidence he proposes to develop; (5) the name and address of the individual who will present his case; and (6) a statement of the approximate length of time his case will take. If the prehearing statement is in conformity with the above requirements, the person shall have the right to participate as a party. In accordance with section 6(c) of the Administrative Procedure Act, industry committee shall, after considering the advice of committee counsel, issue subpoenas authorized by section 9 of the Fair Labor Standards Act of 1938, to parties who make a request therefor accompanied by a clear showing of general relevance and reasonable scope of the evidence sought.

* * * * *

2. As revised, § 511.10 would read as follows:

§ 511.10 Subjects and issues.

(a) The declared policy of the Act with respect to industries or enterprises in Puerto Rico, the Virgin Islands, and American Samoa engaged in commerce or in the production of goods for commerce is to reach as rapidly as is economically feasible without substantially curtailing employment the object of the minimum wage rate which would apply in each such industry under paragraph (1) or (5) of section 6(a) but for section 6(c). Each industry committee shall recommend to the Administrator the highest minimum wage rates for the industry which it determines, having due regard to economic and competitive conditions, will not substantially curtail employment in the industry and will not give any industry in Puerto Rico, the Virgin Islands, or American Samoa a competitive advantage over any industry in the United States outside of Puerto Rico, the Virgin Islands and American Samoa; except that the committee shall recommend to the Secretary the minimum wage rate prescribed in section 6(a) or 6(b),

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REV. 7-1-52

TELEX VCM Clean — **WIRE MESSAGE**

Dirons-nous que l'essai est bon pour ≥ 50 ppb ?

Teletype ☐ No._____

Telegram ☐ Time Filed_____

Please send following message, subject to the terms of your company, which are hereby agreed to:

~~Parlez~~ Dirons-nous < 50 ppb pour un result de dix ppb.

Ponca City, Oklahoma
April 26, 1974

K. L. Schurter
Saddle Brook, New Jersey

W. R. Sorenson will compile data re residual VCM in PVC pipe and extractability of said VCM. The analytical methods will be written by 4/29/74. WRS will facsimile you a copy of the cover letter with conclusions either 4/29 or 4/30 and will release information only after approval by RWG, JJL & KLS. Heckman, KLS & WRS will get copies of the mailing to McCowin of FDA.

Flynt Kennedy

jma
Chem. Res. Div. - R&D
Charge: 8924-10-27

VRD 0002007583

MCA MANUFACTURING CHEMISTS ASSOCIATION
1825 CONNECTICUT AVENUE, N. W. WASHINGTON, D. C. 20009

FOR RELEASE

CONTACT:
Richard F. Blewitt
(202) 483-6126, ext. 282

For Immediate Release

WASHINGTON, D. C., April 16 -- The Manufacturing Chemists Association (MCA) announced today preliminary indications that vinyl chloride exposure has produced angiosarcoma -- a liver cancer -- in mice at several exposure levels.

Industrial Bio-Test Laboratories, Inc., who are conducting the MCA-administered vinyl chloride animal exposure study, informed MCA that their work -- although very preliminary at this point -- tends to confirm the findings of Professor Cesare Maltoni, an Italian scientist who found that vinyl chloride exposure in rats caused cancer.

MCA immediately notified the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health and the Environmental Protection Agency of the preliminary test results.

In the MCA-administered study, rats, hamsters and mice are being exposed seven hours a day, five days a week, to 2500 parts per million (ppm), 200 ppm and 50 ppm. After seven months of exposure, angiosarcoma has been observed in mice at all levels, but not in rats or hamsters.

(more)

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Professor Maltoni reported at the OSHA hearings on vinyl chloride February 15 that he had observed the liver cancer in rats exposed four hours a day, five days a week, to 250 ppm for up to 12 months. However, he did not find the cancer in testing at the 50 ppm level.

The animal exposure study is continuing. Another MCA-administered study on the chemical, documenting the health experience of present and former employees who have worked with the material, the results of which also will be released, is expected to be completed in the near future. Further vinyl chloride testing is under consideration.

# # #

MCA-3839

(b) *Technical services.* • • •

(1) The builder-developer proposing a new subdivision which will have 10 or more dwelling sites will secure the services of a site planner, architect, landscape architect, or engineer, registered or otherwise certified as qualified in the state in which the subdivision is to be constructed, to provide complete planning, drawings, specifications, and supervision on land, street, utility and grading development.

(2) Complete technical services will be obtained and paid for by the builder-developer with his own funds.

(3) At completion of construction (or when construction will be accomplished in phases, at the end of each phase), the person who is qualified and registered or certified in the state in which the subdivision is to be constructed and is providing supervisory services during the period of work shall notify the FHA County Office in writing that all work has been completed in substantial conformance with the approved plans and specifications.

• • • • •

2. Amend § 1804.67 as follows:

§ 1804.67 Streets.

(a) New subdivisions and expansion of existing subdivisions.

(1) Streets must conform to master street plans, design standards and construction specifications of the applicable public body, city, town, county or state and the requirements of the FHA. Developments with more than 20 sites shall have two accesses available, unless an exception is granted by the State Director.

• • • • •

(42 U.S.C. 1480's: delegation of authority by Sec. of Agri., 38 FR 14944, 14948, 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development, 38 FR 14944, 14952, 7 CFR 2.70).

Dated: April 15, 1974.

FRANK B. ELLIOTT,
Administrator,
Farmers Home Administration.

[FD Doc.74-9152 Filed 4-19-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 310 and 700]

VINYL CHLORIDE AS AN INGREDIENT OF DRUG AND COSMETIC AEROSOL PRODUCTS

Notice of Proposed Rule Making

In the FEDERAL REGISTER of May 17, 1973 (38 FR 12931), the Commissioner of Food and Drugs published a notice of proposed rulemaking for prior-sanctioned polyvinyl chloride (PVC) resin. Polyvinyl chloride is a polymeric resin produced by polymerization of vinyl chloride which was used as a component of food packaging materials prior to the passage of the Food Additive Amendments of 1958 and which has been widely used since that time. Only certain formulations of PVC, however, are prior-sanctioned for use in food packaging and therefore are exempt from classification as food additives and may be used without pre-marketing clearance by the Food and Drug Administration.

Early in 1973, the Food and Drug Administration began receiving reports of possible migration problems of ingredients of PVC bottles then being test marketed for distilled spirits. As a result of further analytical testing, the Commissioner published the May 17, 1973 proposal wherein he concluded that the use of PVC for the packaging of alcoholic foods may cause such foods to be adulterated. No PVC bottles have been used for such purposes since then. After the publication of the proposal, the Commissioner began investigating scientific reports regarding the possible migration of PVC container ingredients to nonalcoholic foods as well. Agency action on this matter and on the earlier proposal is expected to be published shortly in the FEDERAL REGISTER. The Commissioner is also considering the applicability of this information to various drug products packaged in PVC, and to various devices composed in whole or in part of PVC which may come in contact with drug fluids, or which may be inserted or implanted in the human body.

Because of the broad interest in the subject of vinyl chloride by both the public and the scientific community because of its potential as a serious threat to the public health, the Commissioner has undertaken an agency-wide effort to explore the problem in connection with those products within the jurisdiction of the Food and Drug Administration and to fashion the appropriate regulatory actions that should be taken to assure full protection of the public health. Representatives of this agency are also members of a Federal inter-agency task force formed to gather data on the overall effect of vinyl chloride on the total environment and to initiate coordinated action to minimize this impact.

In connection with this search for information, the Commissioner is particularly interested in receiving data in response to the following points relating to the use of polyvinyl chloride in containers for food and cosmetics, and in devices:

(1) The extent of usage of polyvinyl chloride by type of container or container liner and type of product.

(2) The vinyl chloride content in polyvinyl chloride used to manufacture or line various food and cosmetic containers, including description of the methods and extraction systems used to determine this content.

(3) The rate and level of vinyl chloride extraction from the aforementioned containers or their liners by various foods and cosmetics, including data derived after periods of storage.

(4) The rate and level of percutaneous absorption of vinyl chloride from cosmetics and devices when in contact with the skin or mucous membrane.

(5) The vinyl chloride content of various drug fluids after they have been in contact with devices composed in whole or in part of polyvinyl chloride.

(6) The effect on blood and tissues of vinyl chloride extracted from devices composed in whole or in part of polyvinyl chloride inserted or implanted in the body.

All persons in possession of such data are urgently requested to submit it to the Food and Drug Administration in writing (preferably in quintuplicate), if at all possible on or before June 21, 1974. This data should be sent to the Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, MD 20852. Received data may be seen in the above office during working hours, Monday through Friday.

The Commissioner recently received a petition from the Health Research Group, 2000 P Street NW., Washington, D.C. 20036, proposing to prohibit immediately the continued use of vinyl chloride as a constituent or propellant of cosmetic aerosol products and of polyvinyl chloride as a container material for any cosmetic product which can leach out detectable amounts of vinyl chloride from the polyvinyl chloride container material. The petitioner contends that there is substantial evidence that vinyl chloride monomer is carcinogenic.

A copy of the petition and letter of transmittal to the Commissioner are on file in the Office of the Hearing Clerk.

The Commissioner has reviewed all cosmetic product ingredient statements on file with the agency, representing approximately 50 percent of current market formulations, as of February 1, 1974, and has ascertained that no information exists in these files indicating use of vinyl chloride in cosmetic aerosol products. Furthermore, the Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), has informed the Food and Drug Administration that the results of a recent telephone poll, covering 26 companies including the major aerosol hair spray manufacturers, show that no company contacted has manufactured products containing vinyl chloride since June 1973. In 1973, according to this information, two companies produced vinyl chloride-containing products with a total volume of approximately 1,625,000 units. The CTFA estimates that the percentage of hair spray cans manufactured in 1973 which contained vinyl chloride is less than 0.4 percent. A copy of the information received from the CTFA is on file in the Office of the Hearing Clerk.

There is no known past or present usage of vinyl chloride as a propellant in food aerosol products. Any such use without a food additive regulation would be a violation of the Federal Food, Drug, and Cosmetic Act.

With regard to drug products, the Food and Drug Administration has recently reviewed its files and conducted a survey of all known drug manufacturers of aerosol products to determine the extent to which vinyl chloride is used as a component, including propellant, in such products. The only known use of vinyl chloride in drug products has been as a

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propellant in aerosol preparations. While all the information requested in the survey was not supplied by manufacturers, the review of the agency files and preliminary results of the survey indicate that vinyl chloride is not currently being used in aerosol drug products. There are no approved new drug applications for vinyl chloride as a component of any drug. There is evidence, however, that manufacturers of some over-the-counter drug products used vinyl chloride as a propellant until 1973.

To determine the full extent that vinyl chloride is used in drug products and to determine if any additional action is needed to protect the public, there is published elsewhere in this issue of the FEDERAL REGISTER, a notice, pursuant to § 132.7(a)(4) (21 CFR 132.7(a)(4)), of the regulations under the Drug Listing Act of 1972, requiring all registrants to submit a list of all drug products marketed containing the ingredient vinyl chloride or packaged in containers composed of or lined with polyvinyl chloride.

The Commissioner has determined that there are sufficient scientific data on which to base a decision that: (1) vinyl chloride presents an unnecessary hazard to the public health when it is used as an ingredient in cosmetic aerosol products and that such use should be banned, and (2) vinyl chloride, when used as an ingredient in drug aerosol products, is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act, and requires an approved new drug application as a condition of marketing.

There is ample evidence that vinyl chloride inhalation can result in acute toxicity manifested by an array of symptoms, including unconsciousness as a result of high concentration of inhalation. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported in animals. Reported studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Of most significance, however, is the fact that vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride to PVC. The scientific articles providing this evidence are on file in the Office of the Hearing Clerk. In view of this evidence, the Commissioner concludes that the banning of vinyl chloride as an ingredient in drug and cosmetic aerosol products is required. These products are often used in the confines of a small room where the level of vinyl chloride to which the individual may be exposed, although usually only for a short time, could be significantly in excess of the safe level established in connection with occupational exposure.

As a corollary to this conclusion, the Commissioner has requested all known manufacturers of such products with supplies still on the market to recall these supplies from the market to the retail level, and similar requests will be made of any additional such manufacturers if and as they are located.

Two cosmetic aerosol hair spray manufacturers commenced such recalls as of April 2, 1974 and a drug and cosmetic manufacturer, identified after a file search, began recall of seven drug and three cosmetic aerosol products as of April 8, 1974, following an April 4, 1974 request.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 601(a), 701(a); 52 Stat. 1050–1055, as amended; 21 U.S.C. 352, 355, 361(a), 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that Parts 310 and 700 be amended as follows:

1. By adding a new § 310.506 to Subpart E of Part 310 to read as follows:

§ 310.506 Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products.

(a) Vinyl chloride has been used as a propellant in aerosol drug preparations. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have been reported in animals. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Recently, vinyl chloride has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride.

(b) The Commissioner finds that there is a lack of general recognition by qualified experts of the safety or effectiveness of aerosol drug preparations containing vinyl chloride as an ingredient, including propellant. Therefore, any such product containing vinyl chloride is a new drug and a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that such preparations are safe and effective for the purposes intended.

(d) Any such drug within the jurisdiction of the act which is not in accord with this regulation is subject to regulatory action.

2. By adding a new § 700.14 to Subpart B of Part 700 to read as follows:

§ 700.14 Use of vinyl chloride as an ingredient, including propellant of cosmetic aerosol products.

(a) Vinyl chloride has been used as an ingredient in cosmetic aerosol products including hair sprays. Where such aerosol products are used in the confines of a small room, as is often the case, the level of vinyl chloride to which the individual may be exposed could be significantly in excess of the safe level established in connection with occupational exposure. Evidence indicates that vinyl chloride inhalation can result in acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Furthermore, vinyl chloride has recently been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride. It is the view of the Commissioner that vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Any cosmetic aerosol product containing vinyl chloride as an ingredient shipped within the jurisdiction of the act is subject to regulatory action.

Interested persons may, on or before May 22, 1974, file with the Hearing Clerk, Food and Drug Administration, room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: April 16, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–9232 Filed 4–19–74;8:45 am]

DEPARTMENT OF TRANSPORTATION

COAST GUARD

[33 CFR Part 117]

[CGD 74115]

NEW RIVER SOUND AND STRANAHAN RIVER, FLA.

Proposed Drawbridge Operation Regulations

At the request of the Florida Yacht Club Council, the Coast Guard is considering revoking the regulations for the East Las Olas Boulevard drawbridge across the Atlantic Intracoastal Waterway in Fort Lauderdale, Florida, to require that the draw open on signal. Present regulations allow closed periods from November 15 through May 15 from 7 a.m. to 6 p.m. during which the draw need only open on the hour and half hour. This change is being considered for the following reasons:

(a) The regulations presently in force were issued on March 15, 1950 (15 FR 1461), and were amended on July 2, 1953 (18 FR 3782), October 28, 1955 (20 FR 8118), and October 20, 1956 (21 FR 8084). These regulations were issued to ease ve-

the denial order issued against the respondent on February 28, 1972 (37 FR 5306).

Dated: April 12, 1976.

RAUER H. MEYER,
Director,
Office of Export Administration.

[FR Doc.74-9080 Filed 4-19-74;8:45 am]

COMPUTER SYSTEMS TECHNICAL ADVISORY COMMITTEE

Notice of Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given that a meeting of the Licensing Procedures Subgroup of the Computer Systems Technical Advisory Committee will be held Monday, April 29, 1974, at 1:30 p.m. in Conference Room A, Main Commerce Building, 14th and Constitution Avenue, Washington, D.C.

Members advise the Office of Export Administration, Bureau of East-West Trade, with respect to questions involving technical matters, worldwide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to computer systems, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls.

Agenda items are as follows:

1. Opening remarks by the Chairman, Computer Systems Technical Advisory Committee.
2. Appointment of subgroup chairman.
3. Presentation of papers or comments by the public.
4. Discussion of export licensing procedures relating to computer systems.
5. Executive Session: Continuation of discussion of export licensing procedures.

The public will be permitted to attend the discussion of agenda items 1-4, and a limited number of seats will be available to the public for these agenda items. To the extent time permits, members of the public may present oral statements to the subgroup. Interested persons are also invited to file written statements with the subgroup.

With respect to agenda item 5, "Executive Session," the Assistant Secretary of Commerce for Administration, on December 20, 1973, determined, pursuant to section 10(d) of Public Law 92-463, that this agenda item should be exempt from the provisions of sections 10 (a)(1) and (a)(3), relating to open meetings and public participation therein, because the meeting will be concerned with matters listed in 5 U.S.C. 552(b)(1).

Further information may be obtained from John L. Collins, Chairman, Computer Systems Technical Advisory Committee, IBM World Trade Corporation, 1001 K Street NW., Washington, D.C. 20006 (A/C 202-833-6000).

Minutes of those portions of the meeting which are open to the public will be available 30 days from the date of the meeting upon written request addressed to: Central Reference and Records Inspection Facility, U.S. Department of Commerce, Washington, D.C. 20230.

Dated: April 17, 1974.

RAUER H. MEYER,
Director, Office of Export Administration, Bureau of East-West Trade, Department of Commerce.

[FR Doc.74-9099 Filed 4-19-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[NADA No. 48-236V]

AGRITRONICS CORP.

Agritronics Swine Premix T-S; Withdrawal of Approval of New Animal Drug Application

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351; 21 U.S.C. 360b) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), the following notice is issued:

Agritronics Corp., 511 24th St., Des Moines, IA 50311, has requested that its NADA (new animal drug application) No. 48-236V be withdrawn in accordance with § 135.28(d) (21 CFR 135.28(d)) on the grounds that the drug is not being marketed. Notice is given that approval of NADA No. 48-236V for Agritronics Swine Premix T-S, which contains tylosin and sulfamethazine, is hereby withdrawn.

Effective date. This notice shall be effective April 22, 1974.

Dated: April 15, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-9114 Filed 4-19-74;8:45 am]

HUMAN DRUGS CONTAINING VINYL CHLORIDE OR PACKAGED IN POLYVINYL CHLORIDE CONTAINERS

Notice to Drug Manufacturers, Packers, and Distributors

Elsewhere in this issue of the FEDERAL REGISTER (39 FR 14215) the Commissioner of Food and Drugs has proposed that all aerosol drug products containing vinyl chloride as a component, including propellant, are new drugs and subject to regulatory proceedings unless the products are the subject of new drug applications approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act. That proposal is based on scientific data demonstrating that vinyl chloride is not generally recognized as safe and effective as a component, including propellant, of a drug product.

The Food and Drug Administration is aware that vinyl chloride has been used as a propellant in aerosol drug preparations, but has no information that vinyl chloride is currently being used in the manufacture of drug products. There is ample evidence that vinyl chloride inhalation can result in acute toxicity manifested by an array of symptoms including unconsciousness as a result of high concentration inhalation. Cardiac effects, bone changes, and degenerative changes in the brain, liver, and kidneys have also been reported in animals. In addition, there are studies demonstrating the carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride, and it has been linked to liver disease, including liver cancer, in workers engaged in the polymerization of the monomer to polyvinyl chloride.

Polyvinyl chloride, a polymeric resin produced by polymerization of vinyl chloride, is used in drug packaging materials. There is evidence of vinyl chloride migration when polyvinyl chloride is used in packaging material for products containing alcohol. There have also been reports of the possible migration of polyvinyl chloride container ingredients to non-alcoholic products as well. Because of this it is necessary to give special study to such packaging material to determine if it is safe for its intended use.

For these reasons it is essential that the Commissioner have knowledge of every drug product currently marketed in the United States that contains vinyl chloride as an ingredient, and information regarding every marketed drug product packaged in a polyvinyl chloride container or in a container lined with polyvinyl chloride. Such information is necessary for determining if there is adequate evidence whether drugs containing vinyl chloride or packaged in containers composed of, or lined with, polyvinyl chloride are safe and effective for their intended purposes and what action, if any, is required to protect the public health.

Section 510(j)(3) of the act, as added by the Drug Listing Act of 1972, authorizes the Commissioner to require each registrant under section 510 of the act to submit a list of each drug product which the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution and which contains a particular ingredient, when the Commissioner has made a finding that the submission of such a list is necessary to carry out the purposes of the act. For the reasons stated above the Commissioner so finds with regard to drugs containing vinyl chloride. As packaging materials are an integral part of the drug product, the Commissioner also so finds with regard to drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners.

In addition to the required list of drugs containing vinyl chloride and a required list of drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners, the Commissioner is requesting, but not requiring, that certain other information be submitted. The Commissioner acknowledges that some of the information being requested has also been requested in the regulations implementing the Drug Listing Act of 1972, and will be available

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from that source. However, it will greatly simplify the compilation of this information if it is included in this submission.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 510, 701(a), 52 Stat. 1040–1042, as amended, 1053, as amended, 1055, as amended; 21 U.S.C. 321, 360, 371(a); 42 U.S.C. 262) and under authority delegated to the Commissioner (21 CFR 2.120), each registrant under section 510 of the act is required to submit to the Food and Drug Administration a list of all human drugs which are being manufactured, prepared, propagated, compounded, or processed for commercial distribution and which contain vinyl chloride whether or not the vinyl chloride is an active or inactive ingredient and a list of all human drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners as follows:

1. Reporting firm name, address, and registration number.

2. List of drugs containing vinyl chloride (by trade name, if any, and established name, if any) and a list of drug products for which polyvinyl chloride is used as a container or a container liner (by trade name, if any, and established name, if any).

It is requested but not required that the following information also be submitted:

3. National Drug Code (NDC) if one has been assigned.

4. A statement whether the drug is marketed over the counter or limited to prescription distribution.

5. Route of administration.

6. Amount of vinyl chloride in average daily dose.

7. Quantity of drug distributed (number of dosage units) during previous 12 months.

8. A copy of the label and labeling.

In addition to the information requested in items 1 through 8 (excluding item 6) for drug products packaged in polyvinyl chloride containers or in containers with polyvinyl chloride liners it is requested, but not required, that the following information be submitted.

9. A statement of the vinyl chloride content in polyvinyl chloride used for the manufacture of the drug container or container lining. Include description of the methods and extraction systems used to determine this content. If this information is not known, provide the name and address of the drug container or container liner supplier and/or manufacturer.

10. The rate and level of extraction of vinyl chloride from the polyvinyl chloride containers or container liners by the particular drug or by any other extraction or solvent systems, including data derived after periods of storage. Where such information is not known, but is or may be available from the supplier or manufacturer of the container or liner, provide the name and address of such supplier or manufacturer.

11. The rate and level of absorption of vinyl chloride as an ingredient or of vinyl chloride extracted from a polyvinyl chloride container or liner by the drug contained on an average daily dose. Where such information is not known, but is or may be available from the supplier or manufacturer of the container or liner, provide the name and address of such supplier or manufacturer.

12. Name and address of the manufacturer of the polyvinyl chloride resin, where such information is known.

This information shall be submitted to:

Department of Health, Education, and Welfare
Food and Drug Administration
Bureau of Drugs, Drug Listing Staff (HFD–7)
5600 Fishers Lane
Rockville, MD 20852

by May 22, 1974.

Dated: April 15, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.74–9231 Filed 4–19–74;8:45 am]

ADVISORY COMMITTEES

Notice of Meetings

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463, 86 Stat. 770–776; 5 U.S.C. App.), the Food and Drug Administration announces the following public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a) (1) and (2) of the act:

Committee name	Date, time, place	Type of meeting and contact person
1. Panel on Review of Internal Analgesic including Antirheumatic Drugs.	May 8 and 9, 9 a.m., Conference Room C, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open May 8, 9 a.m. to 10 a.m., closed May 8, after 10 a.m., closed May 9. Lee Geismar, Room 10B–05, 5600 Fishers Lane, Rockville, Md. 20852, 301–443–4960.

Purpose. Reviews and evaluates available information concerning safety and effectiveness of active ingredients of currently marketed non-prescription drug products containing internal analgesic agents.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continuing review of nonprescription internal analgesic drugs under investigation.

Committee name	Date, time, place	Type of meeting and contact person
2. Panel on Review of Orthopaedic Devices	May 11, 9 a.m., Hotel Utah Motor Lodge, Salt Lake City, Utah.	Open 9 a.m. to 10 a.m., closed after 10 a.m. James R. Veale (HFM–120), 5600 Fishers Lane, Rockville, Md. 20852, 301–443–3550.

Purpose. Reviews and evaluates available data concerning safety, effectiveness, and reliability of orthopaedic devices currently in use.

Agenda. Open session: Comments and presentations by interested persons. Closed session: Continuation of review of previous classification results and identification of specific areas for standards for those devices classified as requiring standards.

Committee name	Date, time, place	Type of meeting and contact person
3. Panel on Review of Dental Devices.	May 22 and 23, 9 a.m., American Dental Association Bldg., Chicago, Ill.	Open May 22, 9 a.m. to 10 a.m., closed May 22 after 10 a.m., closed May 23. Robert S. Kennedy, Ph.D., (HFM–120) 5600 Fishers Lane, Rockville, Md. 20852, 301–443–2370.

Purpose. Reviews and evaluates available data concerning the safety, effectiveness, and reliability of dental devices currently in use.

Agenda. Open session: Comments and presentations by interested persons; device classification; and device legislation. Closed session: Continuing review and classification of dental devices.

Agenda items are subject to change as priorities dictate.

During the open sessions shown above, interested persons may present relevant information or views orally to any committee for its consideration. Information or views submitted to any committee in writing before or during a meeting shall also be considered by the committee.

A list of committee members and summary minutes of meetings may be obtained from the contact person for the committee both for meetings open to the public and those meetings closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act.

Most Food and Drug Administration advisory committees are created to advise the Commissioner of Food and Drugs on pending regulatory matters. Recommendations made by the committees on these matters are intended to result in action under the Federal Food, Drug, and Cosmetic Act, and these committees thus necessarily participate with the Commissioner in exercising his law enforcement responsibilities.

The Freedom of Information Act recognized that the premature disclosure of regulatory plans, or indeed internal discussions of alternative regulatory approaches to a specific problem, could have adverse effects upon both public and private interests. Congress recognized that such plans, even when finalized, may not be made fully available in advance of the effective date without damage to such interests, and therefore provided for this type of discussion to remain confidential. Thus, law enforcement activities have long been recognized as a legitimate subject for confidential consideration.

These committees often must consider trade secrets and other confidential information submitted by particular manufacturers which the Food and Drug Administration by law may not disclose, and which Congress has included within the exemptions from the Freedom of Information Act. Such information includes safety and effectiveness information, product formulation, and manufacturing methods and procedures, all

VRD 0002007588

VRD 000207589

TRIP REPORT

PLACE: SPI Meeting, Washington Hilton, Washington, D. C.

SUBJECT: VCM Toxicity and SPI Involvement

ATTENDED BY: R. W. Gerwig
F. Kennedy

DATE: April 16, 1974

The meeting was chaired by Tony Viltone, Goodrich, and after considerable discussion a committee was appointed. Harry Conners, Diamond Shamrock, will chair the committee whose members include R. W. Gerwig, Conoco; Joe Fath, Tenneco; Lee Kuhn, Stauffer; Joe Jageman, Pantesote; Art Steele, Union Carbide; and persons to be designated from Dow, Goodrich and Waugatauh. A steering committee composed of Ross Adams, Air Products; Harry Couner, Diamond Shamrock; Jim Williams, Dow; Joe Fath, Tenneco; and Tony Viltone, Goodrich, was also appointed.

The committee was assigned the following tasks as related to preparing an industry position for presentation to OSHA:

1. Collect human health data from all plants with at least 20 years of operation.

2. Recommend a time oriented type of standard for VCM exposure.

3. Monitor the MCA animal exposure studies and recommend and support additional studies.

4. Define standards; i.e., the techniques, methods and hardware recommended.

5. Recommend VCM content of resin shipped. Industry took position that polymer could contain less than 0.1% VCM; labor's position was 0.01% VCM or less.

6. A sub-committee of the main committee will accumulate data regarding fabricator exposure. Fabricator companies should not be identified when data are submitted to the committee.

Ross Adams, Air Products, will contact A. D. Little and other candidates regarding the preparation of the economic impact of a zero-level regulation from OSHA. Preliminary indication from A. D. Little was a $60,000-$80,000 cost and 6 to 8 weeks.

VRD 000200759

TRIP REPORT
SPI Meeting, Washington, D. C.
VCM Toxicity and SPI Involvement
April 16, 1974

Viltone stated that ORC (Organization of Research Councilors) had retained Georgetown University to do a mortality study covering the fabricating industry. (This study is similar to the MCA sponsored study of the VCM/PVC industry by Tabershaw Cooper.)

Residual VCM in Polymer

Several companies mentioned the residual VCM in their product lines and apply to values "out of bag or car."

Stauffer - emulsion is less than 20 ppm, low molecular weight emulsion 800-1600 ppm, high molecular weight 300-600 ppm.

Air Products - pearls 10-50 ppm, pipe type syspension 1000+, copolymer 300-400 ppm.

Goodrich - man process - coarse fraction, above 1000 ppm, fine fraction 200-300 ppm.

Union Carbide - suspension - "goes down to unmeasurable level."

Pantesote - rigid calendered sheet, 10-85 ppm, resin shipped at 100 ppm goes to 5-10 ppm, lab extruder "at end of pipe found 500 ppm."

Everyone agreed that VCM weathered from resin reasonably easily.

Shut Down Levels

R. W. Gerwig indicated Conoco could operate at 20 ppm level (question probably referred to ceiling not TWA); Goodrich, Carbide and a few others could at 30 ppm; the remainder could operate at either 40 or 50 ppm, more at 50 ppm.

Jim Williams, Dow, told several people that Dow's VCM plants operated at 10 TWA, 25 ceiling, and 50 evacuation and that V. K. Rowe had made that same recommendation to John Stender, Assistant Secretary of Labor, on Monday in response to a telephone call by Stender. Such a standard would be much better than establishing a ceiling limit at lower levels as the emergency temporary standard did.

Flynt Kennedy

jms
4/23/74
c: RWG-JDBu-JJL-KLS-JDBr-LNV-WRS-DVP-(EAS-REL)

(1) M-Z for RWG FK JJL JFG HRF

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

JOSEPH E. KELLER
EROME H. HECKMAN
CHARLES M. NEEHAN
WILLIAM H. BORGHESANI, JR
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
EDWIN B. SPIEVACK
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH

April 16, 1974

Dr. Karl A. Hochschwender
American Hoechst Corporation
Route 202-206 North Bridgewater
Post Office Box 2500
Somerville, New Jersey 08876

Re: Proposed Regulation of Food-Contact Articles in the Household; 39 Fed. Reg. 13285, et seq.

Dear Karl:

We have reported several times recently that FDA was considering the revocation of the so-called "housewares exemption" under which utensils, dinnerware and similar articles used in the home were exempt from the Food Additives Amendment of 1958. The formal FDA action in this connection by means of a proposed Rule Making was published in the Federal Register on April 12, 1974. We are enclosing copies of the pertinent pages from the Federal Register for your ready reference. It will be apparent to you that in this proposed Rule Making the Food and Drug Administration is asserting jurisdiction over dinnerware, utensils and other housewares, but is also once again reaffirming that if a substance does not migrate under intended conditions of use, it is not a food additive.

As we see it, in its citation of legislative history in the preamble to this proposal, the Food and Drug Administration has gone to almost tortuous care to rationalize away and thereby minimize the significance of the explicit statements expressing Congressional intent to the effect that dinnerware or utensils were not intended to be the subject of coverage under the 1958 Food

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Additives Amendment. Nevertheless, we believe that in light of recent Supreme Court decisions, it is not unreasonable to anticipate that the FDA position would be upheld by the courts should its jurisdiction be challenged in a case in which a health hazard was shown to exist.

Although the Food and Drug Administration refers to "no migration" in the preamble, and uses the statutory definition of a food additive in the proposed regulation which implies that a substance that does not migrate is not a food additive, FDA still has not defined "no migration" in operational terms. In following up on this, I discussed the situation in some detail and was advised by Peter B. Hutt, Assistant General Counsel of the Department of Health, Education and Welfare (in effect, General Counsel for FDA) that the time might be appropriate for filing a Food Additive Petition that would effectively define "zero migration" for indirect additives.

It is our intention to prepare such a Petition promptly to be able to circulate a draft along with draft Comments on the subject proposed Rule Making for your consideration. In this connection, we are requesting those receiving copies of this letter who wish to do so to submit to us your suggestions for the preparation of Comments. In order to circulate draft Comments and leave time to prepare final Comments within the permitted sixty day period, we are requesting your initial responses by May 1, 1974.

We plan to circulate draft Comments embodying any recommendations we might receive and a draft Petition to establish a "zero" standard for migration as close to May 15 as we can. In the meantime, as we await your suggestions, we hope that those of you who have any questions will not hesitate to contact us.

Cordially yours,

Enclosures

cc: To All Members of SPI Food, Drug
and Cosmetic Packaging Materials Committee

VRD 0002007596

in Puerto Rico, including Industry Committees Nos. 118, 119-A, 119-B, 120-A, 120-B, 121-A, 121-B, and 121-C and gave notice of dates of investigations and hearings.

The purpose of the hearings was to review the wage rates in those industries which were below $1.60, the then highest minimum rate under the Fair Labor Standards Act, except in agriculture where minimum rates below $1.30 were to be considered. Under section 5(d) of the Act, the Secretary is obliged to furnish to such committees such data as he has available on the matters referred to the committees. Section 511.6, Title 29, Code of Federal Regulations prescribes the use of surveys. As the result of the enactment of the Fair Labor Standards Amendments of 1974, Pub. L. No. 93-259, April 8, 1974, the data obtained in surveys in industries are now inadequate; the criteria for use in recommending wage rates are changed substantially, and the hotel and restaurant industries wage rates have been increased to those in the various States.

Accordingly, pursuant to section 5 of the Fair Labor Standards Act of 1938 (29 U.S.C. 205) as amended, Reorganization Plan No. 6 of 1950 (3 CFR 1949-53 Comp. p. 1004), and 29 CFR Part 511, I postpone the meetings of Industry Committees Nos. 118, 119-A, 119-B, 120-A, 120-B, and 121-A. New dates for the convening of the postponed industry committees will be published in the FEDERAL REGISTER within the next few weeks. These industry committees will hold their meetings within the period between September 1, 1974 and December 15, 1974. Industry Committees Nos. 121-B and 121-C for the Hotels and Restaurant Industries are dissolved.

Signed at Washington, D.C., this 9th of April 1974.

PETER J. BRENNAN,
Secretary of Labor.

[FR Doc.74-8482 Filed 4-11-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

SUBSTANCES IN FOOD-CONTACT ARTICLES IN THE HOUSEHOLD, FOOD SERVICE ESTABLISHMENTS, AND FOOD DISPENSING EQUIPMENT

Food Additive Status

Since enactment of the Food Additives Amendment of 1958 (September 6, 1958, Pub. L. 85-929, 72 Stat. 1784), letters and oral opinions have at times been issued by personnel of the Food and Drug Administration advising that ordinary houseware articles such as cutting boards, pots and pans, and eating utensils, as well as agents used to clean such housewares, are not subject to regulation under section 409 of the Federal Food, Drug, and Cosmetic Act (72 Stat. 1785; 21 U.S.C. 348). The FDA has also had a well-established regulatory policy that lead (or other heavy metals) in pottery dinnerware, in enamelware, or in pewter articles, which may migrate to food held in the dinnerware (or enamelware or pewter) and poison the consumer, is subject to regulation as a "food additive" within the meaning of section 201(s) of the act (21 U.S.C. 321). Food additive regulations have been promulgated governing numerous substances used in food-contact surfaces, and in sanitizing solutions for such food-contact surfaces, in 21 CFR Part 121, Subpart F.

Because of resulting confusion with regard to the applicability of the Federal Food, Drug, and Cosmetic Act to various houseware, food service, and food dispensing products, including cleaning agents, the Commissioner has determined that it is in the interest of efficient enforcement of the act to promulgate a regulation articulating the scope of the food additive provisions of the act with regard to such products.

The definition of a food additive is extremely broad and easily covers all substances which may reasonably be expected to migrate to food from food-contact articles. Section 201(s) provides that:

> The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; * * *), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures * * * to be safe under the conditions of its intended use; * * *

This statutory language provides no basis for an exemption for any houseware, food service, or food dispensing article or cleaning agent, and shows clearly that Congress meant to regulate all substances not generally recognized by experts as having been shown to be safe which become or which may reasonably be expected to become, directly or indirectly, a component of any food unless specifically exempted by section 201(s). (Although color additives are specifically exempted from the definition of food additives by section 201(s)(3), they are regulated by sections 706 and 402(c) of the act (21 U.S.C. 376, 342) regardless of intended use. See 21 CFR 8.1(f).)

The legislative history of the Food Additives Amendment of 1958 also shows that Congress recognized and intended that all substances which may reasonably be expected to become a component of any food are "food additives" (unless specifically exempt under section 201(s) of the act). Both the House and Senate Reports on the Food Additives Amendment of 1958 contain the following text (House Report No. 2284, 85th Cong., 2d sess., p. 3, July 28, 1958; Senate Report No. 2422, 85th Cong., 2d sess., p. 5, August 18, 1958):

> The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."
>
> The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."
>
> The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.
>
> On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by this legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food.

These statements make it clear that Congress intended to regulate all substances (except those generally recognized as safe or specifically exempted by section 201(s) of the act) which become or which may become a component of food by any means other than purely accidental contamination.

The House Select Committee to Investigate the Use of Chemicals in Food and Cosmetics which originally recommended a food additives amendment showed a similar desire for providing the strongest possible consumer protection through comprehensive food additive legislation. The committee's report to the Congress (House Report No. 2356, 82d Cong., 2d sess.), recommended:

> * * * the [food additive] legislation should provide that evidence that the chemical is safe, and does not produce harmful chemical reactions in the end food product, should be submitted to the Food and Drug Administration for clearance before the chemical is utilized.

Several manufacturers of food packaging and wrapping materials testified at the hearings on the Food Additives Amendment of 1958 and, while some favored and others opposed the legislation, it was generally recognized that substances used to package and hold food would be subject to the new legislation where migration occurred. See, for example, the statement by Frederick S. Leinbach, representing the American Paper & Pulp Association, "the overall national association of the paper and pulp industry," speaking with regard to packaging materials:

> If there are extractables, if those materials could reasonably be expected to become a component of the packaged food, they then become additives, and we feel they should be treated as additives. [Hearings Before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, Eighty-fifth Congress, on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food.]

Congressman John Bell Williams, the chairman of the subcommittee which prepared the food additive legislation, reflected this understanding in the congressional debate on the bill:

> Since the food additive bill, H.R. 13254, passed the House, I have received an inquiry as to how this legislation affects the packaging industry. Of course, packaging

Implications re detergents ??

ordinarily is not intended or reasonably expected to become a part of food and therefore would not come under the bill. The term "otherwise affecting the characteristics of any food" refers to an effect not generally recognized as safe among experts qualified by scientific training and experience to evaluate the safety of food additives; but innocuous effects of packaging, such as protection from dirt, retarding moisture loss, preserving shape, providing convenience in use, handling, and storage, and the like, would not be covered. [Congressional Record of August 23, 1958, 85th Cong., 2d sess.]

Similarly, Congressman Williams also stated that ordinary housewares would not be subject to the new law:

This bill is not intended, for example, to give the Food and Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils. [Congressional Record, 104:17418.]

Thus, ordinary inert articles from which no migration to food occurs are clearly not subject to the act, but there was no congressional intent to exempt all food-contact articles used in the household, food service establishments, and food dispensing equipment.

Other provisions of section 409 of the act also manifest a strong congressional desire to regulate all intended uses of food additives. Section 409(a) provides that:

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe • • • unless—

(1) it and its use or intended use conform to the terms of an exemption • • • pursuant to subsection (i) [for investigational use] • • •; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

Section 409(b) provides that:

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall • • • contain—

• • • • • •

(B) a statement of the conditions of the proposed use of such additive • • •

• • • • • •

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; • • •

These sections are clear. They give no indication that some intended uses are to be regulated while others are not. To the contrary, they show a definite Congressional concern for additives in or on food regardless of how they got there.

When Congress intended to exempt certain substances from the coverage of the act it had no difficulty making such intent readily apparent. Thus, in section 201(s) of the act it specifically provided that the term "food additive" does not include:

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to • • • [September 6, 1958] pursuant to this Act, the Poultry Products Inspection Act • • • or the Meat Inspection Act • • •; or

(5) a new animal drug.

Had Congress meant to exempt specific articles such as dinnerware and cooking utensils from the coverage of the act, therefore, it would have been a simple matter for it to do so.

Finally, section 409(c)(5) of the act provides that:

In determining • • • whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

• • • • •

(B) the cumulative effect of such additive in the diet of man • • •

It is not possible to make an accurate determination of the cumulative effect of an additive without taking into account all means by which that additive may reasonably be expected to enter man's diet. Any reports of adverse effects resulting from migration of unsafe chemical additives from articles such as dinnerware and eating utensils would require prompt regulatory action. Therefore, to exempt dinnerware, eating utensils and other houseware, food service, and food dispensing articles which may reasonably be expected to contribute significant amounts of harmful additives at the final and, arguably, most critical stage of food processing (i.e., immediately before being ingested by the consumer) at the very time when technological advancements have vastly improved methods of detection and evaluation of their effect in man, would be in direct conflict with the express mandate of section 409(c)(5)(B) of the act.

On January 17, 1974, Judge John Feikens of the United States District Court for the Eastern District of Michigan handed down an opinion in *United States v. Articles of food • • • pottery*, holding that pottery dinnerware is subject to the food additive and food requirements of the act:

The legislative history leading to the Food Additives Amendment of the Act shows a clear Congressional intent that substances which are subject to being ingested by human beings be cause of migration are "food additives" and thus "foods" within the meaning of the Act. • • • It is likewise clear that ordinary packaging or food holding devices from which there is no migration are not subject to the Act.

For these reasons, and in the interest of public health, the Commissioner of Food and Drugs has concluded that any prior statements by FDA which conflict with this notice are erroneous and contrary to the Congressional intent as plainly expressed in the act, and any such statements are hereby withdrawn.

The Commissioner recognizes that as a matter of fairness, transitional provisions to implement this proposed regulation are appropriate, since members of industry may presently be marketing certain products bearing migratory substances without an applicable food additive regulation, in reliance upon a prior statement from FDA that the act was not applicable to the product. The proposal therefore provides that by December 31, 1974, manufacturers must either be in compliance with existing regulations or have filed a food additive petition covering the use of a given substance or article. Of course, if there is no migration of a substance to food, or if the substance is generally recognized as safe at the level of migration under the conditions of use involved, the substance is not a food additive and no petition is required. An opinion with respect to migration or GRAS status may be obtained from the Food and Drug Administration upon request.

No transition period is justified, however, for migratory substances in pottery dinnerware, enamelware, or pewter. FDA has for several years conducted a widely publicized regulatory program against such products. Accordingly, the proposal explicitly states that there is no moratorium on food additive charges where migratory substances are found in pottery dinnerware, enamelware, or pewter.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 72 Stat. 1784–1788, 52 Stat. 1055–1056; 21 U.S.C. 321(s), 348, 371(a)), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend 21 CFR Part 121 by adding a new § 121.14, as follows:

§ 121.14 Food additive status of food-contact articles intended for use in the household, food service establishments, and food dispensing equipment.

(a) Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food is subject to the food provisions of the Federal Food, Drug, and Cosmetic Act and, if it is not generally recognized as safe or exempt under section 201(s)(1)–(4) of the act, to the food additive provisions of the act. This includes any substance in food-contact articles whether intended for use in the household, food service establishments, or food dispensing equipment.

(b) Except as provided in paragraphs (c) and (d) of this section, a food additive in a food-contact article intended for any of the uses referred to in paragraph (a) of this section shall, not later than December 31, 1974, be the subject of a food additive regulation or a food additive petition filed with the Food and Drug Administration covering such use. The filing of such a food additive petition shall stay the effective date of this section until the petition is granted or denied.

(c) The transitional provisions in paragraph (b) of this section shall not apply to:

(1) Migratory substances in pottery dinnerware, enamelware, or pewter;

(2) Any migrating substance which is a poisonous or deleterious substance under section 402(a)(1) of the act; or

('ood additives in food packaging and wrapping materials used to package, hold, or otherwise contain food prior to ultimate purchase by the consumer.

(d) Any oral or written opinions contrary to this section are hereby revoked and superseded.

Interested persons may, on or before June , 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: April 5, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-8424 Filed 4-11-74;8:45 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 571]

[Docket No. 74-16; Notice 1]

MOTOR VEHICLE SAFETY STANDARDS

Proposed Modification of Requirements for Motor-Driven Cycles

This notice proposes amendments of 49 CFR 571.108, 571.122, and 571.123, Motor Vehicle Safety Standards Nos. 108, 122, and 123, that would modify current requirements applicable to motor-driven cycles.

The National Highway Traffic Safety Administration has been petitioned by Cycles Peugeot, Ateliers de la Motobecane, and S.I.N.F.A.C. for "(1) recognition of the power-assisted bicycle as a separate category of motor vehicle and (2) promulgation of safety standards for the bicycle appropriate to its low power and speed." Similar petitions have been filed by Bermuda Bikes, Inc. and Robert F. Smith, who are retail dealers of low-powered two-wheeled vehicles.

These vehicles are currently classified as "motor-driven cycles", a subcategory of "motorcycle" that is defined by 49 CFR 571.3(b) as "a motorcycle with a motor that produces 5-brake horsepower or less". As such they are required to meet Federal motor vehicle safety standards, most importantly the ones covering lights (No. 108), hydraulic brake systems (No. 122) and controls and displays (No. 123). Petitioners contend that vehicles which produce no more than 1.5 horsepower deserve a separate classification, and that existing standards applicable to motor-driven cycles are not reasonable, practicable, and appropriate for them.

This agency has decided not to establish a separate category of motor vehicle. The problems of conforming to the standards encountered by vehicles with 1.5 horsepower or less do not appear to be sufficiently different from those of vehicles ween 1.5 and 5 horsepower to justify a separate category. However, this agency has reviewed the requirements applicable to motor-driven cycles in light of the petitions and the renewed public interest in this type of vehicle, and has found that certain minor modifications in the standards may ease the burden of compliance without jeopardizing basic safety performance.

With respect to Standard No. 108, this agency has tentatively determined that in view of the speed and weight characteristics of motor-driven cycles, the problems associated with hand signaling and the lack of turn signal lamps are not as significant as they are with the larger motorcycles. It is therefore proposed that the requirement for turn signals be deleted for motor-driven cycles with a top-speed capability of 30 mph or less. Also, it has been found that low-powered cycle motors may have some difficulty in providing the full required illumination. It is proposed that the required stop-lamp photometric output for low top-speed motor-driven cycles be reduced to one-half that for motorcycles generally. It should be noted that Standard 108 already contains reduced photometric output requirements for motor-driven cycle headlamps.

Because of the low speed of these vehicles, it appears that some modification of Standard No. 122, Motorcycle Braking, would be appropriate. Since fade recovery is not a safety-critical requirement for vehicles with low top speeds, it is proposed that a motorcycle be exempted from the fade requirements of S5.4 if the speed it attains in 1 mile is 30 mi/h or less. Further, since Table I provides no maximum stopping distances below 30 mi/h, values for stops from 25, 20, and 15 mi/h are proposed, maintaining the same deceleration values as required of higher speed stops. For example, a stop from 25 mi/h in the total system effectiveness test would have to be made in not more than 19 feet.

Finally, the NHTSA is proposing an amendment to the Motorcycle Controls and Displays standard, No. 123. Manufacturers of lightweight motor-driven cycles have petitioned that placement of the rear brake control on the left handlebar, rather than at the right foot, be allowed. This deviation from the standardized position for motorcycles would appear to have a minimal detrimental effect, and it is therefore proposed by this notice.

In consideration of the foregoing, it is proposed that 49 CFR Part 571 be amended as follows:

§ 571.103 [Amended]

1. In § 571.103 the following definition would be added to paragraph S3:

"Speed attainable in 1 mile" means the speed attainable by accelerating at maximum rate from a standing start for 1 mile on a level surface.

2. In § 571.108 the following two subparagraphs would be added to paragraph S4:

S4.1.1.— A motor-driven cycle whose speed attainable in 1 mile is 30 mi/h or less need not be equipped with turn signal lamps.

S4.1.1.— A motor-driven cycle whose speed attainable in 1 mile is 30 mi/h or less may be equipped with a stop lamp whose photometric output for the groups of test points specified in Figure 1 is at least one-half of the minimum values set forth in that figure.

§ 571.122 [Amended]

3. In § 571.122, the following sentence would be added to S5.4: "These requirements do not apply to a motorcycle whose speed attainable in 1 mile is 30 mi/h or less."

4. In § 571.122, Table I would be amended to add the following values:

Vehicle test speed miles per hour	Prebumish effectiveness total system (S5.2.1)	Prebumish effectiveness partial mechanical systems (S5.2.2)	Effectiveness total system (S5.4) (S5.7.1)	Effectiveness partial hydraulic systems (S5.7.2)
	I	II	III	IV
15	13	30	11	55
20	24	54	19	44
25	37	84	30	68

§ 571.123 [Amended]

5. In § 571.123, Table I would be amended by revising Item 11, Column 2, to read:

"Right foot control.[1] Left handlebar permissible for motor-driven cycles."

Interested persons are invited to submit comments on the proposal. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5108, 400 Seventh Street, SW., Washington, D.C. 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the comment closing date indicated below will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking. The NHTSA will continue to file relevant material as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Comment closing date: May 13, 1974.

Proposed effective date: 30 days after publication of final rule in FEDERAL REGISTER.

(Sec. 103, 119, Pub. L. 89-563, 80 Stat. 718, 15 U.S.C. 1392, 1407; delegations of authority at 49 CFR 1.51 and 49 CFR 501.8.)

Issued on April 9, 1974.

ROBERT L. CARTER,
Associate Administrator, Motor Vehicle Programs.

[FR Doc.74-8461 Filed 4-11-74;8:45 am]

VRD 0002007663

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Emergency Temporary Standard for Exposure to Vinyl Chloride

1. *Background.* Vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75015, is a synthetic chemical made by oxychlorination of ethylene or by hydrochlorination of acetylene. It is the parent compound of a series of thermoplastic resin polymers and copolymers which are widely used for containers, wrapping tissues, electrical insulation, pipe, conduit and a variety of other products. Vinyl chloride has been made commercially in this country since 1939 and present production is in excess of seven billion pounds per year.

Vinyl chloride (VC) is a gas at ambient temperature and pressure and is a chlorinated hydrocarbon which has moderate liver toxicity. The present standard sets a ceiling value of 500 parts per million (ppm) (29 CFR 1910.93).

On January 27, 1974, the Occupational Safety and Health Administration was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company reported that deaths of several of its employees from a rare form of liver cancer may have been occupationally related. As a result of this notification, and after consultation with NIOSH and a joint inspection of the plant by OSHA, NIOSH, and the Kentucky Department of Labor, a fact-finding hearing on possible hazards involved with the manufacture and use of both VC and polyvinyl chloride was announced on January 30, 1974 (39 FR 3874), and held on February 15, 1974.

2. *Carcinogenicity of VC.* Information produced at the hearing demonstrated that exposure of laboratory animals (mostly Sprague-Dawley rats) to VC by inhalation at and below the current OSHA standard of 500 ppm induced tumors, including angiosarcomas of the liver. Professor Cesare Maltoni, of the Instituto di Oncologia, Bologna, Italy, reported on a series of experiments on the effect of exposure of rats, mice, and hamsters to VC at concentrations of 10,000; 6,000; 2,500; 500; 250; and 50 ppm for varying periods of time (TR 43–63). Some of the experiments have been concluded, and others are still ongoing. The experimental results so far reported are that tumors have been observed in groups of animals exposed to VC at concentrations as low as 250 ppm. No tumors have been observed in the group of animals exposed to VC at a concentration of 50 ppm. It also appears so far that the total number of tumors, as well as the numbers of angiosarcomas of the liver, decrease as the concentrations of VC are reduced to 250 ppm. Finally, another experiment by Professor Maltoni is underway involving the exposure of 300 animals to VC at concentrations of 50 ppm, in order to assess in a more definitive way whether that level of exposure produces tumors in animals. Data reported by Torkelson, Oyen and Rowe (American Industrial Hygiene Association J 22:354–361 (1961)) indicate that exposure to VC at concentrations of 50 ppm failed to induce tumors in rats, hamsters, rabbits, and dogs.

The employees of the B. F. Goodrich Chemical Company who died from angiosarcoma of the liver had an average exposure of approximately 19 years to vinyl chloride, at unknown concentrations, and variable exposures to other volatile chemicals. (TR 93). Some employees of Union Carbide Company and Goodyear Company are also reported in a post-hearing comment from NIOSH dated March 11, 1974, to have had exposure to vinyl chloride and to have died from angiosarcoma of the liver. Finally, autopsies of four deceased employees revealed that liver angiosarcoma tumors were histologically indistinguishable from the angiosarcoma tumors observed in Professor Maltoni's experimental animals. It is concluded therefore, that vinyl chloride is carcinogenic for humans.

We therefore conclude that the present standard for VC should be lowered from a ceiling of 500 ppm to a ceiling of 50 ppm for the following reasons:

(a) In light of the evidence referred to above including the Maltoni experiments demonstrating that VC is carcinogenic in animals at 250 ppm, we conclude that VC must be considered carcinogenic in man at the same level;

(b) Although Professor Maltoni did not induce tumors in his experimental animals at an exposure concentration of 50 ppm, these data do not support the concept that occupational exposure of employees to concentrations of 50 ppm throughout their working lifetime would be without detrimental health effects;

(c) The question whether safe levels of exposure to carcinogens exist for humans and, if so, what such levels would be, is the subject of continuing scientific deliberation. In the case of VC, Professor Maltoni did not observe tumors in his animals at exposure concentrations of 50 ppm. In addition, Torkelson, Oyen, and Rowe found that exposure to concentrations of 50 ppm of VC failed to induce tumors in rats, hamsters, rabbits, and dogs. Accordingly, there is insufficient evidence at this time to conclude that VC at concentrations of 50 ppm or below poses a grave danger to humans.

(d) The emergency temporary standard adopted represents a substantial reduction in the permissible level of exposure and, in our practical judgment, is the lowest level that can be complied with immediately; and

(e) This standard will be in effect for a period of no longer than six months, during which time the whole question of possible safe exposure of humans to VC will be reconsidered more fully and in the light of more information, including experiments which are under way at this time (TR 47, 49, 71–74).

3. *Petitions for an emergency temporary standard.* In a telegram to the Assistant Secretary of Labor, received on or about March 14, 1974, the President of the United Rubber Workers International Union urged the establishment of an emergency temporary standard for VC. During the hearing of February 15, 1974, the Industrial Union Department, AFL–CIO, and the United Rubber Workers International Union made a joint petition for an emergency temporary standard for VC (TR 141–148), which was also joined by the Oil, Chemical and Atomic Workers International Union (TR 37). At the same hearing, several participants urged, on the other hand, a regular rulemaking proceeding as the most suitable for the orderly development of relevant information (TR 112, 180).

The petitions for an emergency temporary standard specified in detail the contents of the standard requested. In substance, the request is to issue a comprehensive fully-developed standard based on the recommendations of the Standards Advisory Committee on Carcinogens submitted to the Assistant Secretary of Labor on or about August 27, 1973. The recommendations are far-ranging, and cover special categories of operations, signs and labels, medical surveillance, reporting, etc., including a permit system for the use of a carcinogen.

We agree that an emergency temporary standard is necessary. We cannot say on the basis of the information developed so far that a comprehensive standard, such as the one requested, is either necessary or even desirable. It has been decided to promulgate a standard containing only those essential provisions which are deemed necessary to provide protection to employees from grave danger until a regular rulemaking proceeding in accordance with sections 6 (b) and (c) of the Act can be concluded. The reasons for a decision to establish a ceiling value of 50 ppm have already been stated. A decision on other possible, appropriate provisions is best made after consideration of all relevant data and views that interested persons may submit during the proceeding soon to be initiated.

With respect to arguments in opposition to issuance of an emergency temporary standard, the concern and efforts of several companies participating at the hearing for the protection of their employees are recognized. It may also be that some employers in some plants have fully complied with the interim controls recommended by NIOSH on January 30, 1974. There is, however, reason to believe that employees are currently being exposed to VC at concentrations well above 50 ppm. This was asserted several times at the hearing, and not seriously questioned. Moreover, a report, dated March 1974, of a survey by the staff of the Office of Standards Development, OSHA, of several facilities manufacturing VC or polyvinyl chloride revealed concentrations for some job classifications as high as 229 ppm. Therefore, a regulation is considered necessary to provide, immediately, adequate protection to workers

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posed to VC. Also, the eight-hour, time-weighted average standard suggested by several participants at the hearing (see, for instance, TR 178), has been rejected. The March 1974 report of the survey revealed that several kinds of work or operations are of short duration. Loading or unloading of a tank car may require approximately 15 minutes. The cleaning of a reactor may require approximately half an hour. An eight-hour, time-weighted average standard would permit exposure to VC at concentrations of 400 ppm for one hour. Such upward excursions, several times the 50 ppm level, cannot be permitted to occur.

4. *The standard.* The standard set out below contains only the requirements deemed necessary to provide protection before the conclusion of the rulemaking proceedings to be commenced shortly.

Because exposure to VC is hazardous, and because such exposure can occur in the processes of synthesizing or polymerizing of VC or in the handling of VC polymers or copolymers which contain absorbed VC, this standard applies to all such processes and to the handling, reaction, manufacturing, processing, releasing, repackaging, or storage of any of these materials. The monitoring requirements serve two purposes, to trigger into operation a compliance program and to check the effectiveness of the program. Also, engineering controls are favored for compliance, and respirators are intended to provide protection until such controls can be installed or in cases where such controls are not feasible.

Accordingly, by reason of the foregoing and on the basis of the record of the hearing of February 15, 1974, with exhibits, the written submissions received before the hearing pursuant to the notice of the hearing, the post-hearing written submissions by the participants at the hearing, the March 1974 report of a fact-finding survey recommendations received from NIOSH, and the other data referred to herein, it is found (1) that VC at concentrations in excess of 50 ppm is physically harmful and carcinogenic; (2) that exposure to VC at concentrations in excess of a concentration of 50 ppm poses a grave danger to employees; (3) that employees are presently exposed to VC at concentrations in excess of 50 ppm; and (4) that the emergency temporary standard set out below is necessary to provide immediate protection to employees from such danger.

Pursuant to section 6(c) of the Occupational Safety and Health Act of 1970, a proceeding will commence shortly in accordance with section 6(b) of the Act, in which the emergency temporary standard will serve as a proposed rule, together with other subsidiary rules. As soon as possible a draft environmental impact statement will be filed with the President's Council on Environmental Quality, and copies will be provided to other appropriate Federal agencies for their comments.

Pursuant to sections 6(c) and 8(c)(3) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1596, 1599; (29 U.S.C. 655, 657)), and Secretary of Labor's Order No. 12-71 (36 FR 8754), 29 CFR Part 1910 is amended by adding thereto a new § 1910.93q to read as set forth below. In addition, pursuant to section 4(b)(2) of the Act (84 Stat. 1592; (29 U.S.C. 653)), the standard in the new § 1910.93q is determined to be more effective than the corresponding standards now in Subpart B of Part 1910, in Parts 1915, 1916, 1917, 1918, and 1926 of title 29, Code of Federal Regulations, and in Part 50-204 of Title 41 of the Code of Federal Regulations. Therefore, these corresponding standards are superseded by the new standard in § 1910.93q.

1. In 29 CFR Part 1910, § 1910.93 is amended by deleting from Table G-1 the line: "* * * C Vinyl chloride * * * 500 * * * 1300".

2. Part 1910 of Title 29 of the Code of Federal Regulations is amended by adding thereto a new § 1910.93q to read as follows:

§ 1910.93q Vinyl chloride.

(a) *Scope and application.* (1) This section applies to any area or operation in which vinyl chloride (chloroethene), Chemical Abstracts Service Registry Number 75015, is manufactured, reacted, handled, processed, released, repacked, or stored.

(2) This section does not apply to the handling, storage, or other use of vinyl chloride polymers and copolymers in the form of fabricated products.

(b) *Permissible exposure.* The occupational environment shall be controlled so that no employee is exposed to vinyl chloride at a concentration in excess of 50 parts per million (ppm) (127.0 mg/cum).

(c) *Monitoring*—(1) *Initial monitoring.* As soon as possible but not later than April 22, 1974, every employer of an employee working in an area or operation in which vinyl chloride is manufactured, reacted, handled, processed, released, repacked, or stored shall begin monitoring the ambient air of the area to determine whether it contains vinyl chloride in concentrations in excess of 50 ppm.

(2) *Frequency.* Monitoring of a sufficient number of employees so that a representative sample of exposures to vinyl chloride may be determined shall be accomplished not less frequently than weekly until all results for three consecutive weeks are at or below 50 ppm. Thereafter, monitoring shall be conducted not less frequently than monthly so long as the concentrations of vinyl chloride do not exceed 50 ppm. If a monitoring sample reveals vinyl chloride in concentrations in excess of 50 ppm, weekly monitoring shall be resumed until all results for three consecutive weeks are at or below 50 ppm.

(3) *Method of monitoring.* Personnel monitoring shall be accomplished by collecting samples by suitable devices worn by the employee. The samples shall be analyzed by gas chromatography or by any other method which is of equivalent sensitivity. The analytical procedure shall be sensitive to 5 ppm of vinyl chloride in air with an accuracy of ±20 percent for a ten minute air sample.

(4) *Employee observation of monitoring.* Employees working in an area or operation whose ambient air is monitored, or their representatives, shall be given a reasonable opportunity to observe the personnel monitoring required by this section.

(5) *Recordkeeping.* The results of all monitoring shall be recorded in writing. The records shall be retained for at least 5 years and shall be made available for inspection and copying by representatives of the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health (NIOSH).

(6) *Employee access.* Each employee and former employee shall have access to such records of the results of monitoring required by this section as will indicate his own exposure to airborne concentrations of vinyl chloride.

(7) *Employee notification.* Each employer shall promptly notify any employee who has been or is being exposed to vinyl chloride in concentrations in excess of 50 ppm, and shall inform him of the corrective action being taken.

(d) *Compliance.* (1) Whenever any monitoring sample reveals vinyl chloride at a concentration in excess of 50 ppm, or whenever any accident, such as rupture of equipment or spillage, indicates the likelihood of a greater than usual release of vinyl chloride into the ambient air, all employees exposed to such concentrations shall be withdrawn to a safe area and shall not be permitted to reenter the work area unless they wear either Type C continuous flow or pressure demand air supplied respirators or self-contained breathing apparatus.

(2) Work which may reasonably be expected to release vinyl chloride in concentrations in excess of 50 ppm, such as repair, maintenance or cleaning of reactors or other equipment containing vinyl chloride, shall be accomplished only by employees wearing Type C continuous flow or pressure demand air supplied respirators or self-contained breathing apparatus.

(3) In any case covered by paragraphs (d)(1) or (d)(2) of this section, in addition to providing the required respirators, the employer shall examine and analyze the source of the excessive concentrations of vinyl chloride in order to determine feasible engineering or operational controls appropriate to reduce the airborne concentrations to the permissible level. Such controls shall be implemented as quickly as possible.

(4) Periodic tests shall be conducted for equipment leaks and for emissions of vinyl chloride which may result from work practices.

3. In 29 CFR Part 1910, § 1910.19 is revised to read as follows:

§ 1910.19 Special provisions for air contaminants.

(a) *Asbestos dust.* Section 1910.93a shall apply to the exposure of every employee to asbestos dust in every employment and place of employment covered by § 1910.12, § 1910.13, § 1910.14, § 1910.15, or § 1910.16, in lieu of any dif-

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ferent standard of exposure to asbestos dust which would otherwise be applicable by virtue of any of those sections.

(b) *Vinyl chloride.* Section 1910.93q shall apply to the exposure of every employee to vinyl chloride in every employment and place of employment covered by § 1910.12, § 1910.13, § 1910.14, § 1910.15, § 1910.16, in lieu of any different standard on exposure to vinyl chloride which would otherwise be applicable by virtue of any of those sections.

Effective date. These amendments shall become effective on April 5, 1974.

(Secs. 4, 6, and 8, 84 Stat. 1592, 1596, 1599 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71, 36 FR 8754.)

Signed at Washington, DC., this 2d day of April 1974.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc.74-7890 Filed 4-4-74;8:45 am]

Title 32A—National Defense, Appendix

CHAPTER X—OFFICE OF OIL AND GAS, DEPARTMENT OF THE INTERIOR

[Oil Import Reg. 1 (Rev. , Amdt. 65)]

OIL IMPORT REG. 1—OIL IMPORT REGULATIONS

Canadian Imports

There appeared in the FEDERAL REGISTER on February 1, 1974 (39 FR 5193) a proposal to amend several sections of Oil Import Regulation 1 (Revision 5) as amended. Amendment 64 to Oil Import Regulation 1 (Revision 5) made the changes related to the proposed rulemaking for all sections except for sections 29 and 33, both of which pertain to Canadian imports. Publication of amendment of sections 29 and 33 was deferred until discussions could be held with the Canadian government to determine their export policy. Those discussions have been concluded. The Canadian government plans to continue to control exports along the lines of their present controls for at least through September 1974 at which time the method of control may be modified significantly. Accordingly, interested parties should note that, although sections 29 and 33 are written to provide allocations for the entire allocation period May 1, 1974 through April 30, 1975, licenses will only be issued initially for one half of the May 1, 1974 through April 30, 1975 allocation period and the licenses will only be valid for a six month period unless extended by the Director. This procedure will provide for needed flexibility should the Canadian export policy change to the extent that it is necessary to further modify the affected sections of the Oil Import Regulation to conform to such changes.

As stated in the preamble to Amendment 64 the three tier system proposed for making allocations under section 29 did not receive complete acceptance. Also, the proposed change to section 29 was predicated on a continuation of the Federal mandatory crude allocation program in its present form. The Federal Energy Office has now proposed changes to that program. For these reasons it has been decided to retain the historical basis for making allocations of Canadian imports into Districts I–IV. The major change is a provision that requires that a person having an allocation of Canadian imports must process the entire volume of Canadian imports in his own facility.

The changes to section 33 are strictly technical in nature with the exception of the licensing periods referred to above.

This amendment also amends section 3 to provide that entries for consumption of Canadian imports by pipeline under a license issued pursuant to these regulations may be made until midnight of May 15, following the end of the allocation period in which the license authorizing such imports from Canada was issued. This fifteen day overlap is necessary to prevent disruption of pipeline operations at the end of each allocation period.

This amendment 65 becomes effective on April 5, 1974.

WILLIAM A. VOGELY,
Acting Deputy Assistant Secretary of the Interior.

Approved

WILLIAM E. SIMON,
Deputy Secretary of the Treasury.

A new paragraph (f) is added to section 3 to read as follows:

Sec. 3. Allocation periods.

* * * * *

(f) Notwithstanding the provisions of paragraphs (a) and (e) of this section entries for consumption of Canadian imports by pipeline may be made until midnight of May 15 following expiration of the allocation period in which a license authorizing such imports from Canada was issued.

Section 29 is amended in its entirety to read as follows:

Sec. 29. Canadian Imports—Districts I–IV.

(a) As used in this section, the term "Canadian imports" means imports from Canada of crude oil which has been produced in Canada and unfinished oils which have been derived from crude oil or natural gas produced in Canada and which have been transported into the United States by overland means or over waterways other than ocean waterways.

(b) To be eligible for an allocation of imports under this section, a person must have in Districts I–IV a facility capable of processing Canadian imports.

(c) The Director shall, in accordance with the terms of paragraph (d)(1) of this section, make allocations for the allocation period May 1, 1974 through April 30, 1975 of not to exceed 762,000 average barrels daily of Canadian imports into Districts I–IV.

(d)(1) The Director shall make allocations not subject to license fees of Canadian imports to eligible applicants who received allocations of such imports for the period January 1, 1973 through December 31, 1973, pursuant to section 23 or from the Oil Import Appeals Board under section 21, or from both. Each such applicant shall be entitled to an allocation of Canadian imports calculated in accordance with the following formula:

$$\frac{\text{Sum of each eligible applicant's allocation of Canadian imports in 1973 pursuant to section 23 and section 21-expressed in barrels per day}}{\text{Sum of all allocations of Canadian imports in 1973 pursuant to section 23 and section 21-expressed in barrels per day}} \times 762{,}000 \text{ barrels/day}$$

(2) The Director shall issue before May 1, 1974 to each eligible applicant a license equal to one half of the allocation calculated pursuant to subparagraph (1) of this paragraph. Such licenses shall expire on October 31, 1974 unless extended by the Director. The Director shall issue before November 1, 1974 a second license to each eligible applicant equal to the remainder of the allocation calculated pursuant to subparagraph (1) of this paragraph. Such licenses shall expire on April 30, 1975.

(e)(1) Except as provided for in subparagraph (2) of this paragraph a person who imports Canadian imports must process all such imports in his own facility. For the purpose of this paragraph, blending by mechanical means does not constitute processing.

(2)(i) Canadian imports may be exchanged on a barrel for barrel basis for other Canadian imports but each person receiving crude oil or unfinished oils in the exchange must process the crude oil or unfinished oil received in his own facilities. Settlements, credits, monetary, or accounting adjustments reflecting the relative values of the oils involved in the exchange are permissible.

(ii) Canadian imports which are sold to meet the requirements of regulations published by the Federal Energy Office shall not be subject to the provisions of paragraph (e) of this section.

(f) If a person who receives an allocation of Canadian imports under this section fails to import the total quantity of imports specified in the allocation, or if he fails to process all such imports for Canadian imports received in exchange for such imports in his facilities before July 1, 1975, or if he fails to meet the requirement of paragraph (e) of this section, then any allocation of Canadian imports for Districts I–IV to which such person may otherwise be entitled for the first allocation period beginning after April 30, 1975 shall be reduced by the Director by the amount of Canadian im-

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FOR IMMEDIATE RELEASE THURSDAY, APRIL 4, 1974

EPA FORMS VINYL CHLORIDE TASK FORCE

The Environmental Protection Agency has formed an internal task force to assess the overall environmental impact of vinyl chloride, a gaseous chemical, and the plastic, polyvinyl chloride.

Vinyl chloride has been implicated in the recently reported deaths of ten workers at plants where the gas is used to produce the polyvinyl chloride. All died from a rare form of cancer, called angiosarcoma of the liver.

The task force, chaired by Glenn E. Schweitzer, Director of EPA's Office of Toxic Substances, is charged with assessing possible environmental and health risks associated with the manufacture, distribution, and disposal of vinyl chloride and polyvinyl chloride.

At present, the task force is reviewing, collecting and assessing data on 1) the ambient emission and effluent levels of vinyl chloride in air and water from vinyl chloride and polyvinyl chloride manufacturing plants 2) the environmental impact of all disposal methods for vinyl chloride and polyvinyl chloride wastes, including landfill, incineration, deep-well injection, and ocean dumping 3) ecological effects of vinyl chloride in the environment.

The task force plans to meet with environmental and consumer groups to discuss its mission and exchange information. A similar meeting has taken place between the task force and the chemical industry. The task force is also working with other Federal

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EPA FORM 1510-1 (REV. 6-72)

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agencies concerned with vinyl chloride, including the Department of Labor; the Department of Health, Education and Welfare; the Consumer Product Safety Commission, and the Department of Commerce.

Vinyl chloride is used as a propellant in 23 pesticide aerosols currently registered by EPA. The gas helps expel the contents from the pesticide containers.

In a March 28 letter to the Health Research Group, a Washingt D.C. based public interest organization, EPA said that it will shortly notify the manufacturers, formulators and distributors of these products of the need to substitute another substance for vinyl chloride. A copy of the letter is attached.

The Agency said that, "Even though the health data for vinyl chloride are limited, we believe that it is prudent public policy for us to request the manufacturers of these pesticides to make a voluntary change..."

If a currently ongoing EPA evaluation of these pesticides indicates a substantial risk or imminent hazard to the user, and if voluntary compliance has not been obtained, the Agency will invoke suspension of the products or other enforceable remedies.

On March 27, EPA mailed letters to the manufacturers giving them ten days in which to state any objections to the Agency's making public the brand names of the 23 products. This period for comment is required since the existence of vinyl chloride in the pesticides may be considered part of the products' confidential formulations.

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TO - NEWS, MEDICAL AND CONSUMER NEWS DESKS

FROM / FDA'S RELATIONS WIRE WASH 347-5155

FOR IMMEDIATE RELEASE 04/30/76

WASHINGTON-- THE FOOD AND DRUG ADMINISTRATION TODAY INITIATED ACTION TO ENSURE THAT VINYL CHLORIDE IS NOT USED IN ANY AEROSOLIZED FOOD, DRUG OR COSMETIC PRODUCT.

VINYL CHLORIDE IS A GASEOUS SUBSTANCE USED TO PRODUCE A TYPE OF PLASTIC CALLED POLYVINYL CHLORIDE /PVC/. IT HAS ALSO BEEN USED AS THE PROPELLANT IN AEROSOL PRODUCTS. THE SUBSTANCE HAS BEEN ASSOCIATED WITH TEN CASES OF A RARE LIVER CANCER AMONG U.S. INDUSTRIAL WORKERS EXPOSED TO THE CHEMICAL OVER EXTENDED PERIODS OF TIME.

THE USE OF VINYL CHLORIDE IN AEROSOL PRODUCTS REGULATED BY FDA HAS BEEN MINIMAL. FDA IS UNAWARE OF ANY PAST OR PRESENT USE OF THE SUBSTANCE IN AEROSOLIZED FOOD PRODUCTS. SUCH USE WOULD REQUIRE PRIOR FDA APPROVAL AND NO SUCH APPROVALS HAVE EVER BEEN GIVEN.

FDA IS ALSO UNAWARE OF ANY PRESENT USE IN AEROSOLIZED COSMETICS OR [illegible]PRODUCTS. THE AGENCY HAS, HOWEVER, WARNED OF THE COSMETIC MANUFACTURERS AND THE DRUG MANUFACTURER WHO USED VINYL CHLORIDE AS A PROPELLANT BEFORE JUNE OF 1973. ALTHOUGH LITTLE IS KNOWN ON THE SUBJECT, FDA IS REQUESTING THE MANUFACTURERS TO RECALL THE PRODUCTS AS A PRECAUTIONARY MEASURE. /SPECIFIC DETAILS ON ANY PRODUCTS BEING RECALLED WILL BE PROVIDED AS THEY ARE DEVELOPED AND PUBLISHED ON FDA'S WEEKLY LIST OF RECALLS./

FDA WILL USE THE DRUG LISTING ACT OF 1972 TO REQUIRE MANUFACTURERS OF DRUGS TO FURNISH INFORMATION ON ANY AEROSOLIZED DRUG PRODUCTS WHICH CONTAIN VINYL CHLORIDE. THE AGENCY IS ALSO WRITING TO ALL KNOWN COSMETIC MANUFACTURERS REQUESTING THEM TO IDENTIFY PRODUCTS WHICH CONTAIN THE SUBSTANCE. RECALLS WILL BE UNDERTAKEN IF NECESSARY.

THE USE OF PVC AS A FOOD PACKAGING MATERIAL HAS BEEN UNDER ACTIVE FDA INVESTIGATION SINCE MAY OF 1975, WHEN THE AGENCY LEARNED THAT VC CONTENT HAD LEACHED FROM PLASTIC LIQUOR BOTTLES INTO THE LIQUOR. FDA INITIALLY PROPOSED A TEN PPM STANDARD OF ALCOHOL-CONTAINING FOOD OR BEVERAGES FOR CONSUMERS. THE BOARD OF ALCOHOL, TOBACCO AND FIREARMS LATER TOOK THE EXPERIMENTAL USE OF SUCH BOTTLES FOR PACKAGING OF WINE.

FDA IS CURRENTLY REVIEWING DATA AND COMMENTS WHICH HAVE BEEN SUBMITTED IN RESPONSE TO THE PROPOSAL. THE AGENCY IS ALSO LOOKING AT OTHER FOODS PACKAGED IN PVC CONTAINERS TO DETERMINE IF A SIMILAR LEACHING [illegible]OBLEM EXISTS.

THE FDA ACTIONS ANNOUNCED TODAY WILL FORMALLY BE ISSUED IN THE FEDERAL REGISTER NEXT WEEK.

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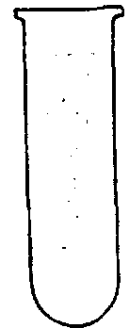
FOR FURTHER INFORMATION CONTACT BERNARD J. DOLAN OF FOOD AND DRUG ADMINISTRATION/ PHONE /301/ 443-3285 OR /HOME/ PHONE /301/ 460-1795. FDA 76-45.

FOOD CHEMICAL NEWS

Editor: Louis Rothschild, Jr.
Managing Editor: Raymond Galant
Assistant to the Editor: Natalie Pargas
Assistant Editor: Eileen Kugler

Circulation Director: Shirley Galant
Production Manager: Dorothy Hill
Associate Editors: Cathy Cooper, Gail Tapscott



VRD 000207616

FDA REGULATION OF INDIRECT ADDITIVES TO BE REAPPRAISED

The Food and Drug Administration is embarking upon a reappraisal of the basic "assumptions" that underlie its regulation of indirect additives, it was disclosed at a March 25 meeting of the agency's National Food Advisory Committee.

The new look at indirect additives -- particularly packaging materials -- was prompted by: (1) unexpected migration problems with acrylonitrile-styrene-butadiene plastic bottles for soft drinks, which may delay use of plastic pop bottles for some time; and (2) possible vinyl chloride monomer migration into food products from rigid polyvinyl chloride containers (See FOOD CHEMICAL NEWS, March 18, Page 23).

Packaging Laboratory Established in Bureau of Foods

Richard Ronk, who is director of food and color additive work in the Bureau of Foods, disclosed that the Bureau has established a Packaging Laboratory to provide guidance in determining whether the system FDA has used for years in regulating indirect additives is satisfactory.

Ronk said that if the present "assumptions" do not prove out, FDA will have to develop a new method of evaluating indirect additives. If, however, the reappraisal indicates that there is no problem, "there are things we shouldn't be doing," he said.

The FDA-er explained that if there are no problems, the agency is spending too much time and money regulating indirect additives, such as adhesives components. "We're not convinced that the system doesn't work," Ronk stressed.

Bureau of Foods Director Dr. Virgil O. Wodicka, confessing to long-term "concern" about indirect additives, said no hazard has been known so far "because of the extent of our ignorance." He commented that this is true despite the fact that the United States has more stringent regulation of indirect additives than any other nation.

Wodicka said, "... There are still many problems ... and many decisions to be made."

Saying that indirect additives comprise "a very complicated area," Ronk said regulation of more than 10,000 indirect additives has been based on "a series of

VRD 082007617

assumptions." For example, he said FDA has relied on use of food-simulating solvents -- distilled water, 3% acetic acid, aqueous ethyl alcohol up to 50%, and heptane . The agency has required extraction in these solvents at 120° F. until equilibrium is reached.

Another assumption, Ronk said, was that the total diet consists of 80% aqueous food, 5% acid food, 5% alcoholic food, and 10% fatty food. "In its time, this was a good system," the FDA-er said, announcing the intention to reappraise the assumptions. However, he noted that there are problems with equilibrium studies, since migration has been detected long after equilibrium was believed to have been reached.

Noting the possible need to "evolve a system," Ronk said that if migrants have to be determined in foods rather than in food-simulating solvents, it will be a "fantastic analytical job."

Wodicka suggested that some of the unexpected migrants found after the equilibrium has been reached might result from de-polymerization on aging.

Wodicka said that he has regarded the review of "generally recognized as safe" substances as an "administrative tidying up of the files," because he expected few problems to arise. However, he expressed doubt about indirect additives, because of the nature of the "foreign" substances and lack of knowledge as to whether the human body possesses enzymes to handle them.

The Bureau Chief added that there is a possibility that a no-effect level modified by a safety factor may be "scientifically naive" in evaluating indirect additives. Wodicka said that FDA is now considering a way to review approved indirect additives.

Acrylonitrile Extractives Found After Six Months

Making the first public disclosure of the acrylonitrile problem, Ronk said that extractables have been found after six months, despite a much earlier equilibrium. Noting that the firm involved will bring in more data, he said that if there is extraction long after equilibrium was thought to be reached, "all of this will have to be held in abeyance." He said a no-effect level of .5 p.p.m. doesn't leave a sufficient margin of safety. Tests by the company indicated residues from migration ranged from 0.3 to 0.5 p.p.m., under the most severe conditions of the study.

Ronk noted the significant economic impact, saying that a number of firms are working on acrylonitrile bottles for soft drinks. He said one clearance has been granted on a Food Additive Petition filed by Standard Oil of Ohio. All of the companies have been notified of the need for new tests on migration, and there is some belief that new work may near completion by one of the six firms considering marketing acrylonitrile bottles.

The FDA-er hailed the acrylonitrile bottle as a "breakthrough in technology," but discussed the residue problem, including possible cyanide residues. Ronk concluded, "I'm sure they will solve the problem."

VRD 000200618

Interim Food Additive Order for PVC Would Set Limits

Regarding the PVC problem, Ronk said an "interim" Food Additive Order might be proposed to limit vinyl chloride to less than 10 p.p.m. in rigid plastic, with a limit in an end test of 50 p.p.b. For PVC films, the limit would be 1 p.p.m. in the film, with an end test limit of 50 p.p.b. The FDA-er said that if all of the vinyl chloride monomer migrated, the total would be less than 50 p.p.b. He also indicated FDA may require establishment of a no-effect level.

Wodicka noted that no interim Order proposal has yet been reviewed at the top levels of his agency.

Ronk reviewed tests made on PVC extracted in heptane for organotin stabilizers, saying it was "too bad" researchers did not look for vinyl chloride monomer at the same time.

He said there was a "significant amount of extractives" of organotin stabilizer, and that a small amount of the stabilizer -- 0.06 p.p.m. -- was still extracting after 14 months in cottonseed oil at 135° F. Ronk indicated this may be predictive of vinyl chloride monomer extraction.

The FDA official said a 1971 Italian study using inhalation indicated that vinyl chloride might be a carcinogen, noting that another Italian study is now underway attempting to reproduce the 1971 results. Carcinogenicity has not been established through ingestion, Wodicka noted.

Statistical Model Could be Used For Methods For Carcinogen

If vinyl chloride proves to be a carcinogen, Ronk said, methodology will have to be developed. Wodicka said the problem would then be one of enforcing "zero." He indicated that, if it were necessary, FDA might use the Mantel-Bryant statistical model, or some variation of it, to determine the needed sensitivity of method to demonstrate no residues of a carcinogen.

FDA proposed adoption of a variation of the Mantel-Bryant method for feed additives, and it was indicated last week that it might be applied to the controversial case of diethylstilbestrol (See story, Page 6)..

Ronk said British data indicate that vinyl chloride can migrate to a fatty food, and that it was also shown to migrate to an aqueous fruit drink. He added that any PVC problem is probably limited to "rigid formulations," and noted that the Society of the Plastics Industry has indicated that migration can be reduced through use of new formulations. He added that in the Italian test, 250 p.p.m. was reported as the lowest no-effect level.

Wodicka raised the question of FDA authority to regulate a finished formulation, noting that the agency has authority to regulate ingredients (food additives). Ronk replied that FDA can prescribe safe conditions of use.

VRD 0002007619

The Bureau Director noted that FDA's limit of polychlorinated biphenyls in paper and paperboard has been stayed, and that the agency's authority to regulate paper has been questioned (See FOOD CHEMICAL NEWS, Feb. 11, Page 22). Wodicka said the outcome of the PCB matter may affect FDA's position on PVC containers.

Ronk predicted that FDA will be "more aggressive" in regulating indirect additives as a result of the knocking out of the old "housewares exemption" (See FOOD CHEMICAL NEWS, Dec. 3, Page 3).

He disclosed that FDA's long-pending proposal to issue a Food Additive Order for synthetic organic colorants in paper and paperboard (See FOOD CHEMICAL NEWS, July 12, 1972, Page 18) has gone back to the drawing board. He said the agency has found that the end-test specified in the proposal does not work. Ronk commented that FDA is now "back to ground zero" on the colorants proposal, and will probably have to work out a listing of approved colorants.

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MANTEL-BRYAN APPROACH MAY BE APPLIED TO DES METHOD

The Food and Drug Administration will ask an ad hoc adivsory group of experts to study the sensitivity of analytical method which would be needed for the continued marketing of diethylstilbestrol.

The deliberations of the group will be based on FDA's controversial proposal under which the sensitivity of analytical methods for carcinogenic animal drugs and other feed additives may be extrapolated from the results of toxicity studies (See FOOD CHEMICAL NEWS, July 23, Page 22). The FDA proposal is a variation of the Mantel-Bryan statistical model.

The question of the needed sensitivity of a method for DES became especially pertinent last week with the March 27 FDA proposal to revoke the official status of currently-used methods, as expected (See FOOD CHEMICAL NEWS, March 25, Page 19). At the same time, FDA urged use of a 14-day withdrawal period rather than a 7-day withdrawal period for DES-medicated feed.

Under the Delaney anti-cancer clause, as it applies to veterinary drugs, a carcinogen may be used only if no residues are left in human food when tested by an officially-approved analytical method. The proposal last week to revoke the official status of the mouse uterine method would leave DES with no place to go in a regulatory sense.

Recommendation by the ad hoc group of a required sensitivity of method would prepare the groundwork for adoption of a new official method which could retain use of DES.

Plans for the ad hoc committee and use of the Mantel-Bryan approach was disclosed March 26 at a meeting of FDA's National Food Advisory Committee by Dr. C. D. Van Houweling, director of FDA's Bureau of Veterinary Medicine. He said he

Occupational Safety and
Health Administration

Barr (202) 961-3914
(Home) (703) 354-0199

VRD 000200762

FOR RELEASE: IMMEDIATE
Friday, March 22, 1974

OSHA ANNOUNCES EMERGENCY MEASURES TO PROTECT WORKERS FROM VINYL CHLORIDE

The Department of Labor announced today it will issue an emergency temporary health standard to protect workers exposed to vinyl chloride while it proceeds with normal rulemaking procedures for a permanent standard.

Assistant Secretary of Labor John H. Stender, head of the Occupational Safety and Health Administration (OSHA), said the emergency standard will reduce permissible exposure levels of workers in industry from 500 parts per million (ppm) to a 50 ppm ceiling, and at the same time require workplace monitoring and, where exposure is greater than the 50 level, personal protective measures and equipment.

The move followed disclosure by officials of the B.F. Goodrich Chemical Co. plant in Louisville, Ky., of a possible connection between vinyl chloride exposure and the deaths of four employees of angiosarcoma--a rare form of liver cancer. One additional death subsequently has been reported from Louisville, and one each from Union Carbide's South Charleston plant and Goodyear's Niagara plant. In addition, two present employees at the Louisville facility have been diagnosed to have angiosarcoma of the liver.

Under the law, the emergency temporary standard serves as a proposed permanent standard. Stender said a proposed permanent standard also would be based on recommendations which have been published by the National Institute for Occupational Safety and Health (NIOSH).

- MORE -

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The proposed permanent standard would establish methods of monitoring work areas for vinyl chloride, set work practices to be followed, institute a medical surveillance program for employees, and require specific personal protective equipment.

It also would prohibit any exposure to vinyl chloride, a substance that is used widely in the manufacture of polyvinyl chloride (PVC), a type of plastic. (Monitoring devices currently available can measure exposures as low as one part per million in air.

The emergency standard, to be published in the Federal Register soon, can remain in effect up to six months. It will be superseded, however, as soon as the permanent standard proposal is adopted.

Stender said that "theoretically, the permanent standard can be on the books as early as June."

"Meanwhile," he continued, "the emergency standard will serve to protect workers from the grave danger we know exists."

Following the report from B.F. Goodrich, OSHA held an emergency fact-finding hearing Feb. 15. Later Stender and other high OSHA officials visited several chemical plants for on-the-spot investigations to determine possible means of limiting worker exposure to vinyl chloride.

Stender said scientific evidence presented at the Feb. 15 hearing by Professor Cesare Maltoni, an Italian scientist, led to the emergency ceiling reduction. Maltoni's studies demonstrated that reduction from 500 to 50 ppm provides a considerable degree of protection from the 250 ppm concentration observed by Maltoni to be cancer-causing in animals, while those exposed only to 50 ppm showed no apparent ill effects.

Stender's visits and meetings followed a field study by a team of OSHA industrial hygienists and chemical engineers at a number of chemical plants in Louisiana to develop technical recommendations.

Although the emergency standard will become effective shortly after publication in the Federal Register, the permanent standard will not be adopted until the public has been given an opportunity to comment and, if requested, a public hearing is held.

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