

Date 8 July 1975

To T. L. Carey/Valley Forge Subject PERSONNEL MONITORING VINYL CHLORIDE
MONOMER AREAS BELOW THE ACTION
From H. L. Watson/Calvert City LEVEL
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cc: J. T. Barr/Valley Forge
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R. E. JONES

In the areas which have been found to be below the action level at the Calvert City Plant, which at this time consist of the Compound Plant and the Emulsion Plant, we have discontinued this week the monthly and personnel monitoring for VCM on employees in these areas.

Unless a process change is made or unless we have cause to believe that the levels of VCM have increased in the area, these levels will remain below the action level and, therefore, are not regulated.

Instead, these areas will be monitored for any and all chemicals for which a TLV exists on a routine basis in accordance with an established program.

John Novak and Ray Feehery will be in the plant Wednesday, and I have asked them to work with Roy McGinnis and Buddy Stermon in outlining a program which can be presented to each superintendent so that he may see that it is done appropriately and thereby meet his responsibilities with respect to these chemicals.

Thereafter, the individual superintendent using the assistance of the Safety Engineer, Roy McGinnis, and the Chief Chemist, Buddy Stermon, will periodically and on a statistical basis check the personnel in their area and document same.

The Group Safety and Health personnel will be responsible to see that these programs get started after the formulation, will be responsible to review the documentation during a regular visit on a one-year basis, and approximately six months thereafter on an annual basis conduct a spot audit in each of the operations, thereby checking results and further verifying the findings of the plant personnel.

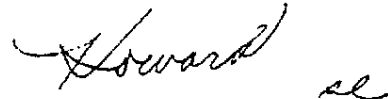
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Subject: PERSONNEL MONITORING VINYL CHLORIDE MONOMER AREAS
BELOW THE ACTION LEVEL

By following the above procedure, we should assure ourselves that the integrity of the plant piping systems is being maintained, that the work places are below the action level in the case of VCM, or the TLV's in the case of the other materials, and we should be able to state in good faith that we have no cause to believe that our areas at any time are above these levels.

It is clearly understood, of course, that should any area during one of these periodic inspections be found to be above the action level for VCM, then we must repeat the process, all in accordance with the written procedure in the OSHA Standard for VCM.


HOWARD L. WATSON

HLW:s1

AP00034353

FDA Weighing Ban On VCM Migration From PVC Into Food

Food and Drug Administration is considering a total ban on contact of vinyl chloride with food. In effect, this would call for zero migration of VCM from polyvinyl chloride packaging into food. The Acting Director of FDA's Bureau of Foods, Howard Roberts, says FDA would recommend such a ban only if current studies prove VCM to be carcinogenic upon ingestion.

It is already known that inhalation of VCM vapors can cause a rare form of liver cancer, angiosarcoma, and Department of Labor has promulgated a workplace standard of one part per million on worker exposure to VCM.

CONTINGENCY PLAN

Mr. Roberts divulged FDA's contingency plan to ban all VCM migration into food last week after Ralph Nader's Health Research Group petitioned the agency on Tuesday (July 1) for an immediate and outright ban on all polyvinyl chloride food packaging.

Pending a final determination on carcinogenicity, Mr. Roberts said FDA will recommend implementation of a regulation "without further delay" imposing a ceiling of fifty parts per billion on vinyl chloride in food.

According to FDA, fifty parts per billion comprises the smallest residue detectable by the most sensitive analytical instruments now available, but the Nader group disputes this.

(An FDA spokesman says, "we have not found a method of analyzing for vinyl chloride that is consistently accurate below fifty parts per billion.")

An HRG lawyer contends that tests can measure VCM accurately below that level, and that in any case no level of carcinogen is permissible in food under the 1958 Delaney Amendment to the Food, Drug & Cosmetic Act.

The HRG petition is based on preliminary findings reported this Spring by an Italian researcher, Cesare Maltoni, showing that some experimental animals developed angiosarcoma when fed VCM. Mr. Roberts says FDA's policy on a total ban is likely to be based on Dr. Maltoni's final report.

FDA itself has been closely studying the

problem of VCM migration in food, and one PVC researcher at FDA who asked not to be identified, told the *Washington Post* that in light of the Maltoni studies: "There should be no detectable levels of vinyl chloride permitted in food."

In December 1974, HEW Secretary Caspar W. Weinberger stated: "The FDA knows of no studies which establish a safe level of consumption when vinyl chloride is leached from containers into packaged food."

HRG claims it has obtained FDA documents showing that large quantities of the chemical appear to leach from plastic wrappings into meat and from rigid containers into vegetable oils, vinegar and personal care products. VCM is stored in the body for long periods of time, leading to accumulation of ingested material.

Society of the Plastics Industry urged "immediate action by FDA to adopt a food additive regulation governing safe use of PVC in food packaging materials" to answer what it says industry considers an "ill-founded" petition by HRG.

SPI SUPPORTS STANDARD

Ralph L. Harding, Jr., SPI president says: "We are advised that FDA is ready to publish a proposed rulemaking which would impose a 'no detectable' criterion on any potential vinyl chloride monomer (VCM) migrating into foods from packaging materials. Industry has been working diligently to provide the technical input and we would support such a standard. Indeed, as a practical matter, it is our firm belief that no migration of vinyl monomer into foodstuffs is taking place now."

Mr. Harding says HRG could have determined "easily" that FDA was preparing to publish its ruling instead of petitioning the agency to prohibit 'vinyl chloride in any amount' in food contact packaging.

The SPI spokesman adds that it has taken some time to develop the supporting data and test methodology but that the information provided to FDA should give assurance that there is no hazard from meats or any other foodstuff packaged in PVC materials.

Similarly, the industry has been working to resolve any problem of vinyl chloride monomer migrating into the packaged food (or cosmetics) and believes that such migration, first detected three years ago when certain liquor was experimentally packaged in PVC, has now been corrected, he says.

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R. E. JONES

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