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RECEIVED DEC 29 1975

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December 22, 1975

No. 9

TO: All Members of VCM/PVC Mailing List

Ladies and Gentlemen:

Following up on our December 19, 1975 letter, and dealing here only with Food and Drug Administration matters, we thought that all of you would be most interested in receiving the following materials:

1. A copy of a press release and set of Comments filed with FDA on Friday by the Council on Wage and Price Stability (CWPS) of the Executive Office of the President. We think you will find the CWPS filing most encouraging.

For example, you might join us in being particularly appreciative of the statement on page 8 that reads "While the benefits of the proposed regulation could very well be non-existent, the costs of compliance are potentially great."

Incidentally, we should also mention here that we were contacted by the Council about two weeks ago and cooperated with Ms. Diane Levine, one of the signers of the Comments, as we would, of course, with any other government agency. More specifically, Ms. Levine was shown a draft of our SPI Comments; also, Dr. Dixler and Joe Hadley of our office spent considerable time with her explaining

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the technical data. We feel the effort was most worthwhile and hope that you will agree.

2. A copy of the SPI press release on our filing, along with the "take" from the press release which we understand moved on the AP wire over the week-end.

3. Having received permission from the publishers of Food Chemical News, reproductions of pages 2 and 36-44 of this week's Edition of that publication. I think many of you must know that Food Chemical News is the publication most widely read by the Food and Drug Administration Staff, as well as those in the food processing and packaging industries.

As you will see, page 2 contains a little note about the Council on Wage and Price Stability Comments, while pages 38-44 will provide you with a press summary of the SPI and Tenneco Comments. We know from our contacts with the publication that other Comments will be afforded coverage next week, and perhaps in subsequent editions as well.

For the moment, we can tell you that, as of today, the Health Research Group (HRG) had not formally filed but its Comments are expected. In accordance with a somewhat peculiar tradition, there is no question but that FDA will accept the HRG filing late, as it is likely to do for others as well. When we have something tangible to report in this respect, we will advise you.

Finally, so some of you will not deem it mysterious, let me just mention that we are including pages

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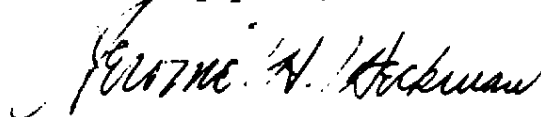
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36 and 37 of this week's Food Chemical News even though the subject matter of the article beginning on page 36 is the proposed acrylonitrile Interim Food Additive Regulation. Frankly, we decided to "piggyback" a little here since copies of this letter go to all members of the Food, Drug and Cosmetic Packaging Materials Committee and many on this SPI standing committee have a vital interest in the AN situation.

You should also be advised that, in accordance with our original plans, complete copies of our two-volume, 925 page set of Comments have been hand-delivered to Mr. Richard Ronk and Mr. Gerad McCowin of the Bureau of Foods; Dr. Robert Schaffner, the Associate Director for Technology of the Bureau of Foods (Dr. Schaffner is known to be working on the PVC problem vis-a-vis cosmetics); and Deputy Associate Commissioner of the Food and Drug Administration, Mr. William F. Randolph.

To say the least, we think the Council on Wage and Price Stability action gives added hope that the new year may be a happier one so, once more, Seasons Greetings!

Cordially yours,



Enclosures

SPI-24574

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CONSUMER-PLASTIC

WASHINGTON (AP) -- THE PLASTICS INDUSTRY TODAY URGED THE FOOD AND DRUG ADMINISTRATION TO WITHDRAW ITS PROPOSED BAN OF MANY TYPES OF POLYVINYL CHLORIDE USED IN FOOD PACKAGING.

THE SOCIETY OF THE PLASTICS INDUSTRY INC. SUBMITTED MORE THAN 300 PAGES OF SCIENTIFIC DATA ASSERTING THAT POLYVINYL CHLORIDE PACKAGING HAS BEEN IMPROVED AND THAT THERE IS LITTLE RISK OF PLASTIC CHEMICALS CONTAMINATING FOOD.

THE FDA PROPOSED LAST SEPT. 3 A BAN ON MATERIALS USED IN SOME PLASTIC BOTTLES, SEMI-RIGID WRAPPINGS AND OTHER CONTAINERS.

THE INDUSTRY URGED THE AGENCY TO SUBSTITUTE A REQUIREMENT THAT ANY POLYVINYL CHLORIDE PACKAGING THAT COMES INTO CONTACT WITH FOOD BE RIGOROUSLY TESTED TO ASSURE THERE IS NO MIGRATION OF THE PLASTIC CHEMICALS INTO THE FOOD.

TEST DATA SUBMITTED BY THE INDUSTRY GROUP WAS SAID TO DEMONSTRATE THAT NO VINYL CHLORIDE MIGRATED INTO LIQUID SOLVENTS FROM PLASTIC BOTTLES, EVEN WHEN SUBJECTED TO EXTREME TIME AND TEMPERATURE CONDITIONS.

THE INDUSTRY ALSO CONTENDED THAT THE FDA IS WITHOUT JURISDICTION TO ESTABLISH AN INTERIM RULE FOR POLYVINYL CHLORIDE WATER PIPES.

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SPI-24575

EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON WAGE AND PRICE STABILITY
726 JACKSON PLACE, N.W.
WASHINGTON, D.C. 20506

FOR IMMEDIATE RELEASE
Friday, December 19, 1975

FOR INFORMATION CALL:
(202) 456-6757

COUNCIL RECOMMENDS DELAY OF
POLYVINYL CHLORIDE PACKAGING REGULATIONS

The Council on Wage and Price Stability today asked the Food and Drug Administration (FDA) to delay proposed regulations banning certain uses of polyvinyl chloride (PVC) for food packaging and evaluate new industry data and technology for use of PVC. Under the proposed regulations, based on now out-of-date production processes, the use of PVC in semi-rigid and rigid containers would be prohibited in food packaging. At present, those kinds of PVC containers are widely used by the food industry as bottle-type containers and sheet wrappings.

The FDA regulations are aimed at preventing the human ingestion of vinyl chloride in the course of food and beverage consumption because of the possibility that the chemical may have carcinogenic effects when ingested. The problem arises because of the potential for vinyl chloride molecules to diffuse from the wrapper into the food or beverage, especially in the case of rigid and semi-rigid containers which have undergone relatively little heating and plasticizing. FDA's proposed regulations were filed in the Federal Register on September 4, 1975, with a request for public comments by December 19.

While agreeing with FDA that the possible ingestion of potentially carcinogenic agents should be regulated, the Council argued that FDA's proposed regulatory response to the problem may now be not only unnecessary but substantially more restrictive, and hence more costly, than is required. The Council based this conclusion, in part, on new technical data submitted by various chemical manufacturers showing that the processes used to produce PVC have changed dramatically in the past few months as a result of industry response to new knowledge about the carcinogenic effects of vinyl chloride as well as industry efforts to comply with the new Occupational Safety and Health Administration (OSHA) worker exposure limits. The FDA regulations are based on the older production processes. The Council also noted that the OSHA worker exposure limits were substantially higher and therefore inconsistent with those FDA would impose. The Council believes that FDA should evaluate these new process to ascertain if the industry claims are accurate.

(MORE)

CWPS-119

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In the absence of this evaluation, the Council concluded that FDA's proposed rules could cause greater than necessary costs because they would potentially prohibit even a minimal, non-injurious presence of vinyl chloride in food. As currently proposed, the rules do not specifically define a minimum amount of vinyl chloride presence necessary to invoke the prohibition. FDA's existing definition of "additive" would apply whenever a container can "reasonably be expected to become a component...of food packaged in the container." No level of reasonableness is defined. The proposed rules for vinyl chloride containers are no more specific. They would apply to any "detectable level of vinyl chloride." According to this standard, the Council argued that FDA was committing itself to the prohibition of infinitesimally small and non-harmful levels of vinyl chloride, at a potentially great cost to the consumer.

After the evaluation, the Council would recommend the promulgation of rules that prohibit the use of PVC in food packaging only when such use results in a specified level of residual concentration in food that exceeds a generally accepted level of health tolerance.

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SPI-24577

BEFORE THE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C.

VINYL CHLORIDE POLYMERS IN
CONTACT WITH FOOD

DOCKET NO. 75N-0190

COMMENTS OF THE COUNCIL ON WAGE AND PRICE STABILITY

The Council on Wage and Price Stability (the "Council") hereby submits its comments on the proposal of the Commissioner of Food and Drugs (FDA) to adopt regulations restricting the uses of vinyl chloride polymers (PVC) in contact with food. These proposed regulations were published, with a request for comment, at 40 Federal Register 40529 (1975). The proposal bans the use of PVC in food packaging where there is a potential for migration of vinyl chloride so as to become a component of food. The use of PVC semi-rigid and rigid containers such as bottles and sheets would therefore be prohibited in food packaging.

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The Council's Interest

The Council was created by the Council on Wage and Price Stability Act of 1974.^{*/} The Council's purpose under the Act is, generally summarized, to monitor, evaluate, publicize, and have a salutary effect on the inflationary impact of activities in both the private and public sectors of the economy. With regard to the public sector, section 3(a) of the Act expressly directs the Council to:

"(7) review and appraise the various programs, policies and activities of the departments and agencies of the United States for the purpose of determining the extent to which those programs and activities are contributing to inflation; and

"(8) intervene and otherwise participate on its own behalf in rulemaking, ratemaking, licensing and other proceedings before any of the departments and agencies of the United States, in order to present its views as to the inflationary impact that might result from the possible outcomes of such proceedings."

The Council does not question the premise on which the proposed regulations rest, that is, that the ingestion of vinyl chloride in the course of food and

^{*/} Public Law 93-387, as amended by Public Law 94-78, 12 U.S.C. 1904 note.

beverage consumption is to be avoided since it is very possible that the chemical may have carcinogenic effects when ingested. The Council staff claims no expertise in the biochemical field that would enable it to question this premise, nor is the Council in favor of deregulating the use of possible carcinogenic agents. We are concerned, however, about regulatory actions on the part of the FDA that may be unnecessary or may be more restrictive than is required to prevent the ingestion of vinyl chloride.

The Proposal

The technical aspects of the PVC problem can be stated as follows:

Vinyl chloride is a chemical with a simple molecular structure which is ordinarily in gaseous form. A process called "polymerization" combines or ties together a large number of these molecules and produces a substance, polyvinyl chloride (PVC), with substantially different characteristics from the original vinyl chloride gas. For example, PVC is a major component in many plastics, and a complete polymerization process yields a PVC which will not dissolve in foods. However, the polymerization process may be incomplete, with the consequence that many single

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vinyl chloride molecules (or "monomers") may become trapped in the interstices of the polymer. These vinyl chloride monomers (VCM) will diffuse from the location of highest concentration (i.e., out of the plastic article) into either the surrounding air or into the food wrapped by the PVC. Most of these monomers are removed during the heating and plasticizing processes in the preparation of packaging material. However, when the resulting PVC product is rigid or semi-rigid, the PVC compound will have undergone relatively little heating and plasticizing. As a result, the rigid or semi-rigid PVC container, if not specifically treated, will contain quantities of these monomers that will be absorbed by foods wrapped in these containers.

According to the published proposal, the FDA has decided to permit PVC coatings and films as wrapping materials for food. Films of polyvinyl chloride were assumed to be one thousandth of an inch (or one "mil") in thickness and contain one part per million (1 ppm) of residual vinyl chloride. If 100 percent of the vinyl chloride monomers migrated into the food which they wrap, then for an average food package the concentration of

vinyl chloride would be two parts per billion (2 ppb).^{*/}

Another Federal agency, the Occupational Safety and Health Administration (OSHA) has promulgated exposure limits providing that "no employee may be exposed to vinyl chloride at concentrations greater than 1 ppm averaged over any eight hour period" or greater than 5 ppm in the air over a 15 minute period.^{**/} OSHA, therefore, must feel confident that 1 ppm of vinyl chloride in air is safe. It should be noted that ingestion of vinyl chloride due to a PVC wrapper is an occasional occurrence, while inhalation is a continuous process. It would appear, then, by implication, that in the FDA's opinion a concentration of 2 ppb or 1 ppb of vinyl chloride monomer in food is an acceptable risk. In OSHA's view, an even higher concentration would

^{*/} 40 Federal Register 40531 (1975).

These calculations were provided by FDA in the preamble to the regulations. It was assumed that 10 grams of food contact each square inch of film, the film weighs 20 milligrams per square inch per mil thickness, and the film contains 1 ppm residual vinyl chloride (20 milligrams x 1 ppm 10 = .020 grams x .000001 = 2 ppb). The assumption of 100 percent migration is, of course, a gross exaggeration, since at least one half of the residual vinyl chloride will diffuse into the surrounding air.

^{**/} See 29 C.F.R. Section 1910.1017c.

be permissible. Even so, the FDA might appear perfectly justified in raising questions about food containers that would lead to concentration levels in excess of 1 or 2 ppb. Accordingly, FDA would appear justified in banning the PVC food-contact articles that precipitated the instant regulations.^{*/} Such articles would presumably impart much more residual vinyl chloride to the food than would PVC films.

We at the Council do not take issue with these conclusions. However, we have been informed by various chemical manufacturers that the processes used to produce PVC have changed dramatically in the past few months as a result of industry response to new knowledge about the carcinogenic effects of vinyl chloride as well as industry efforts to comply with the OSHA worker exposure limits just described. It is claimed that these new techniques produce PVC rigid and semi-rigid containers that contain only 0.35 ppm of residual vinyl chloride.

Moreover, the Council has reviewed recent test

^{*/} According to the FDA in the preamble to the regulation, these articles range in thickness from 7 to 30 mils and may contain up to 180 ppm of residual vinyl chloride. See 40 Federal Register at 40531.

data submitted to the Society of the Plastics Industry by chemical manufacturers.^{*/} These data suggest a level of concentration of vinyl chloride that is below that detectable (with any reasonable degree of confidence) by existing, state-of-the-art measuring devices - 20 ppb. These results were obtained from food-stimulating solvents that were stored in PVC bottles and semi-rigid containers. These tests utilized various storage periods, low volumes of food relative to PVC surface, as well as elevated periods, low volumes of food relative to PVC surface, as well as elevated temperatures that hasten the diffusion process and exaggerate the likely conditions of use so as to maximize the resulting concentration of VCM in a solvent. Theoretical work by chemists at these chemical companies provide a gross estimate that the maximum concentration of residual vinyl chloride in food could not exceed 2 ppb.^{**/} Again This estimate utilizes assumptions that exaggerate VCM concentration in food.

^{*/} We presume that these test results will accompany comments to be filed by the Society on December 19, 1975 in response to the proposed regulation.

^{**/} We presume that these data will also be submitted in the instant proceeding.

If this data is correct, then accepting the FDA's (1-2 ppb) permissible VCM concentration level, and accepting OSHA's VCM standard, we can be fairly certain that no health benefits are to be derived from the proposed regulation.

While the benefits of the proposed regulation could very well be non-existent, the costs of compliance are potentially great. The FDA has prepared an inflation impact assessment of the proposed ban on PVC rigid and semi-rigid food containers. They have determined that the costs imposed upon industry would not be in excess of \$19 million, approximately 38 percent of the revenue generated by the banned PVC.^{*/}

The major problem with the FDA cost analysis is the assumption that the costs of the proposed ban on PVC in certain food containers can be calculated by looking

*/ The FDA's cost estimates were derived by taking that portion of revenue which represents fixed costs, including return on capital investment for the plastics industry. The remaining 62 percent, or variable costs, were excluded because these costs are assumed to be incurred only when the PVC items are produced. Actually, the FDA questioned whether the entire \$19 million would represent a cost of the proposed regulation since it was felt that production would simply switch to other materials such as polystyrene, acrylonitrile copolymer, polyester and nylon/polyester laminates, polypropylene, polyolefin, et cetera.

only at the non-variable costs of producing this PVC. This kind of approach implies that as long as resources can be shifted to other uses, there is no loss when a product that people prefer is banned by government edict. If this "no loss" assumption were true then the product could not have been "preferred." It is precisely those qualities which make the item preferred and the satisfaction which consumers would otherwise obtain from those qualities that is the real cost of such a ban.

In the case of PVC food containers the relevant measurement of the cost of regulatory compliance is the incremental cost of producing a substitute packaging material that has all the virtues of PVC and no additional disadvantages. If no such material exists then development costs or some measurement of the value placed on the unattainable virtues of PVC must be included in the calculation of regulatory costs. The FDA does mention many inadequacies of substitute materials but makes no effort to arrive at the costs of producing the substitutes or to estimate the "losses" to be incurred because of the shortcomings of these substitutes.

One major purchaser of PVC resins and fabricator of PVC containers estimates that alternative materials

would cost 16 percent more than PVC and, in addition, that the shelf life of affected food packages would be reduced by one-third. Retooling costs as well as additional research costs are anticipated.

The FDA inflation impact assessment ignores the capital costs of new equipment, process modification, retooling of fabricating equipment, as well as research and development insofar as these costs will impact over the economy immediately even though they are financed by the firms over a period of years. Although the segment of revenues allocated to pay capital costs of relevant PVC production is less than \$19 million, actual capital costs in the year or two following promulgation by the regulation may be many times that amount. The resources required by the mandated capital expenditures will have to be diverted from other uses in that year or two even though the financing is spread out over many years.

In the Council's view, the proposed rules will cause greater than necessary costs because they would potentially prohibit even a minimal, non-injurious presence of vinyl chloride in food. As currently proposed, the rules do not specifically define a minimum amount of

vinyl chloride presence necessary to invoke the prohibition. FDA's existing definition of "additive" would apply whenever a container can "reasonably be expected to become a component . . . of food packaged in the container." See 21 C.F.R. Section 121.1(e). No level of reasonableness is defined. The proposed rules for vinyl chloride containers are no more specific. They would apply to any "detectable level of vinyl chloride." See proposed Section 121.106(e)(4)(ii). While current measurement devices can detect vinyl chloride monomers in food at concentrations of 20 ppb., it is very likely that future measurement techniques will be able to detect the monomers at much lower concentrations -- for example, at the concentration level that might result from PVC films or in the extreme at concentration levels of one part per trillion or one part per "quadrillion." The FDA proposal would then apparently prohibit even these minimal presences of vinyl chloride.^{*/}

^{*/} Other FDA regulations under the Act also use the unspecific term "detectable" with the same result. See, for example, 21 C.F.R. Section 121.106(d)(2) (dulcin), (d)(3) (P-4000), (d)(5) (cyclamate), (d)(7) (monochloroacetic acid), (d)(8) (thiourea), (d)(11) (DEPC), (c)(1) (Flectol H), (e)(2)(4, 4' - Methylenebis, and (e)(3) (Mercaptoimidazole).

The Council therefore recommends that the FDA delay the promulgation of its proposed rules until it has evaluated more current technical data about the presence of PVC in food. Then, the Council would recommend the promulgation of rules that prohibit the use of PVC in food packaging only when such use results in a specified level of residual concentration in food that exceeds a generally accepted level of health tolerance.

Respectfully submitted,

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Director

James C. Miller III
Assistant Director for
Government Operations
and Research

Vaughn C. Williams
General Counsel

Dianne Levine
Economist

Date:

FOR IMMEDIATE RELEASE: (Friday, December 19, 1975)

SPI ASKS FDA TO DROP PVC RULES: ADOPT ALTERNATIVE SAFETY STANDARDS

NEW YORK, N.Y., Dec. 19 -- More than 300 pages of new data which show that polyvinyl chloride (PVC) packaging has been improved "dramatically" and therefore presents no true risk of vinyl chloride monomer (VCM) migrating into foods packaged in PVC were submitted to the Food and Drug Administration today by The Society of the Plastics Industry, Inc. (SPI).

SPI called on the federal agency to drop its proposed rules on food packaging issued September 3 and reassess its position based on the scientific data furnished to it by the industry.

Specifically, SPI asked FDA to abandon its proposed ban on materials used to make PVC bottles, blister packs and semi-rigid wraps and substitute new regulatory language that will require that any PVC plastic used in food contact applications must pass rigorous tests that assure no reasonable expectation of vinyl chloride monomer (VCM) migration into food.

If FDA heeds the new information given to it by the plastics industry, SPI said, "objectivity will compel the conclusion that it would be wholly unsound to ban any PVC product complying with the new limitations. "

(more)

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SPI-24590

The industry brief also asked FDA to:

1. Grant "positive" prior sanctioned status to PVC gaskets, can liners, flexible tubing, films and certain coatings whose safety was affirmed in the proposed regulations of September 3.

2. Satisfy itself on the complete safety of PVC potable water pipe and then abandon a proposed interim rule for PVC pipe on the grounds there is no health hazard as well as no FDA jurisdiction, to regulate piping systems. (Regulating water pipe is usually under control of local authorities and the Environmental Protection Agency.)

The substitute regulatory language proposed by the industry, would require that "any food contact article made in whole or part of vinyl chloride ... would have to be manufactured so that no vinyl chloride monomer could reasonably be expected to become a component of any food ..."

Basically, SPI contends that vinyl chloride content in today's PVC has been so drastically reduced as to be "not a consequential factor," and that the testing further confirms there is no reasonable expectation that vinyl chloride may become a component of food packaged in PVC.

Test data included in the SPI brief showed that when bottles containing less than one part per million of VCM were tested under exaggerated time and temperature conditions, no monomer could be detected as migrating into the full-range of food simulating solvents.

POLYCHLORINATED BIPHENYL zero limit from water discharges is expected to be announced by EPA today (Dec. 22) (See FOOD CHEMICAL NEWS, Dec. 15, Page 29).

SUMMARY JUDGMENT suit was filed last week by the Natural Resources Defense Council in a District of Columbia Federal Court asking that FDA's four acrylonitrile Orders (§§121.2625, 121.2629, 121.2633 and 121.2524) be declared null and void because no final Environmental Impact Statement has been issued for plastic beverage bottles (See story, Page 36).

PVC regulation delay was asked Dec. 19 by the Council on Wage and Price Stability, which argued that FDA's proposed regulatory response "may now be not only unnecessary but substantially more restrictive, and hence more costly, than is required" (See story, Page 28).

SILVER-PLATED hollowware action levels, announced last week by FDA in letters to participants at the agency's informal meeting on problems of leachable lead (See FOOD CHEMICAL NEWS, Jan. 13, Page 56) will be: (1) 0.5 p.p.m. leachable lead from baby cups or other articles intended for use by infants; and (2) 7 p.p.m. leachable lead for all other hollowware normally used for holding liquid type foods for extended periods of time.

NET WEIGHT appeals court decisions upholding the concept of "reasonable variations" in net weight during distribution are being appealed to the Supreme Court by California local weights and measures officials, as expected (See FOOD CHEMICAL NEWS, Dec. 1, Page 34).

FDA COMMISSIONER SCHMIDT is scheduled to appear on CBS-TV's Face the Nation on Dec. 28.

FDA ADVISORY COMMITTEE industrial memberships are "unsuitable" because of the "conflict of interest issue" except "in the case of special committees with no regulatory implications," Associate Commissioner for Science Dr. Lloyd B. Tepper told Dr. Robert Harkins of the Grocery Manufacturer of America at a Dec. 9 meeting. According to a memo of the meeting written by Tepper, the FDA-er said an example of a special committee on which industry members are appropriate is the National Center for Toxicological Research Science Advisory Board.

ANNUAL INSPECTION of "high risk" establishments by FDA will not include inspection of meat and poultry plants (See FOOD CHEMICAL NEWS, Dec. 8, Page 3). Dr. Robert Angelotti, Associate Director for Compliance in FDA's Bureau of Foods, included meat and poultry establishments in the category of establishments which "pose a greater potential health hazard" and are therefore "high risk" in his speech before the Food and Drug Law Institute. The FDA-er did not imply that his agency intended to take over any of the inspection authority from USDA.

NUTRITION LABELING of Miller Brewing's Lite Beer was questioned by California attorney Marsha N. Cohen in a letter to FDA Associate Commissioner for Compliance Sam D. Fine. She said the product's labeling "is not in compliance with FDA rules ... in that it fails to reveal the percentage of the so-called 'required' nutrients, but only lists the content of calories, protein, carbohydrates, and fats."

NUTRITION LABELING - How It Can Work for You, a 134-page booklet on how to use information from food labels, has been published by the National Nutritional Consortium.

PETITIONS: INSECTICIDE; FORMALDEHYDE TREATED FAT

A Food Additive Petition filed by Ciba-Geigy, and noted by the Environmental Protection Agency Dec. 16, would clear diazinon for spot and/or crack and crevice treatments in food handling establishments.

The establishments covered by the Petition include food service, manufacturing, and processing establishments, such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants and canneries. Treatment with the insecticide - - 0,0-diethyl 0-(isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate - - would also be cleared for animal feed handling establishments, including feed manufacturing and processing establishments, such as stores, supermarkets, dairies, meat slaughtering and packing plants and canneries.

On the same day, EPA proposed exempting from tolerance requirements more inert (or occasionally active) adjuvants for pesticide formulations. These exemptions would apply by cross-reference to food additive tolerance requirements under §121.102 for adjuvants for pesticide chemicals.

The proposal, which is open for comments and advisory committee requests until Jan. 15, would exempt one adjuvant for pesticide formulations used on growing crops or raw agricultural commodities after harvest, 6 adjuvants for formulations used on growing crops only, and 7 adjuvants for formulations applied to animals. EPA also proposed revising the exemption for paraformaldehyde as a preservative for formulations used on growing crops to change the quantitative limit from not more than 1% to not more than 2% of pesticide formulations.

A Petition filed by Alta Lipids, and noted Dec. 17 by the Food and Drug Administration, would clear "formaldehyde-treated animal fat and protein constituents of ruminant feed supplements to increase the consumption rate of animal fat, and for improvement of the handling characteristics of animal fats, respectively."

FINE SAYS INTERIM ACRYLONITRILE PROPOSAL WILL BE FINALIZED IN JANUARY

Associate Commissioner for Compliance Sam D. Fine told the Natural Resources Defense Council recently that the Food and Drug Administration will finalize in January interim proposals on the use of acrylonitrile (See FOOD CHEMICAL NEWS, Nov. 14, 1974, Page 33).

Fine said the long delay has been caused in part by efforts of FDA to develop a uniform method of analysis for detection of acrylonitrile monomer, noting that the four recently issued Food Additive Orders were based on Petitions containing three different methods of analysis.

The work on developing a uniform method for acrylonitrile has been delayed, he continued in a letter to NRDC's Marcia Cleveland, "by the more pressing need to develop better methods of detecting vinyl chloride."

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FOOD CHEMICAL NEWS

Final Regulation Will Not Contain Uniform Method for Detecting Monomer

"Because of this delay," he said, "we have decided to issue the interim food additive regulation without completing work on the uniform method of analysis."

Cleveland had complained that FDA's failure to promulgate the regulations in final form for one year was an "unreasonable delay, and unlawful withholding of agency action." She also complained that FDA's use of the proposed regulations as the basis for approving uses proposed in the four Food Additive Petitions, without making the regulations "final or incorporating the 0.3 p.p.m. limit on acrylonitrile monomer, is arbitrary and capricious" (See FOOD CHEMICAL NEWS, Nov. 24, Page 14).

NRDC filed two suits against FDA to halt use of acrylonitrile bottles for soft drinks and beer, contending that the safety of the substance had not been proved and that FDA had failed to issue a final Environmental Impact Statement on the use of the plastic bottles (See FOOD CHEMICAL NEWS, Nov. 10, Page 47).

In her letter to Fine, Cleveland had demanded that the regulations be finalized or all of the clearances be withdrawn by Dec. 1.

Fine said the interim regulations will be published in January, and will be made effective on publication.

Indicating that FDA would like to move more swiftly on regulations, Fine explained, "Our limited resources do not permit more rapid consideration of the issues raised in the public comments, and final regulations will necessarily continue to follow proposals by a considerable length of time."

In this instance, Fine said, he did not consider the delay "unreasonable," pointing out that most of the studies to be required by the interim food additive regulations are already underway.

He also pointed out that the restrictions on migration embodied in the proposed interim food additive regulations have been explicitly carried over in all subsequently adopted regulations permitting the use of acrylonitrile copolymers.

He noted that the preamble of each regulation contains a statement that these will be amended to cross-reference the requirements of the interim food additive regulation when it is made final, explaining that "this cross-reference is for the purpose of making continued use of the copolymers subject to the requirement for additional testing of acrylonitrile, however, and not to impose limits on permissible migration."

Fine said FDA disagrees with Cleveland's statement that there are no data adequate to support the 0.3 p.p.m. limit on monomer migration proposed for all acrylonitrile uses.

"This issue was discussed in the preamble to the proposed regulation, where it was pointed out that data do exist to establish a tentative no-effect level," the Associate

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Commissioner said, adding, "While definitive data are being sought, we consider the available data adequate to support the measures taken."

SPI URGES FDA TO DEAL WITH PVC THROUGH CMP. PRIOR SANCTION REGULATIONS

The Society of the Plastics Industry has urged the Food and Drug Administration to abandon its detailed proposals, and deal with polyvinyl chloride and the problem of vinyl chloride monomer (VCM) through an amendment of the Good Manufacturing Practices regulation for incidental additives (§121.2500) and through establishment of its proposed §121.2009 reaffirming the "prior sanction" for PVC uses.

In comprehensive comments submitted late last week on the proposals (See FOOD CHEMICAL NEWS, Dec. 15, Page 41), the Society urged FDA to "(1) take full cognizance of the way in which polyvinyl chloride and products have been changed dramatically since significant parts of the data base for the FDA proposal were acquired; (2) study closely the extensive scientific evidence which is of the essence of this pleading...; and (3) reassess its proposals on the basis of the far more current information presented..."

SPI also called for a reassessment of the legal and jurisdictional questions involved.

SPI noted that it "has no objection whatsoever to this filing being treated as a Petition for a Prior Sanction Affirmation Regulation, or a Generally Recognized as Safe (GRAS) status Regulation, so long as marketing disruptions are avoided by immediate action," adding: "Indeed, this kind of approach would be eminently acceptable should FDA consider it preferable."

The Society argued that the data assembled by its member companies and presented in appendices to its comments illustrate that vinyl chloride monomer cannot "reasonably be expected" to migrate to food from vinyl chloride articles produced using the new manufacturing processes and techniques developed by the industry.

It suggested that FDA amend the good manufacturing provisions for incidental additives to provide that:

"Any food contact article made in whole or in part of a vinyl chloride monomer based plastic shall, in addition to any other requirements or limitations, be so manufactured that no vinyl chloride monomer may be reasonably expected to become a component of food under the intended conditions of use of that article."

Further, SPI suggested that the Subpart E provisions for prior sanctioned food ingredients be amended by addition of a new section, as follows:

"§121.2009 Vinyl chloride polymer resins. Polyvinyl chloride resins consist of basic resins produced by the polymerization of vinyl chloride. Polyvinyl chloride basic resins have a maximum volatility of not over 3 percent when heated for 1 hour at 105° C. as determined by ASTM Method D 3030-72, and an inherent viscosity of not less than 0.35 as

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determined by ASTM Methods D 1243-66. Vinyl chloride copolymer resins are the polymers produced by the copolymerization of vinyl chloride with other monomeric substances. x x x

The proposed prior sanction affirmation would cover all uses of polyvinyl chloride resins, i.e., can enamels, conveyor belt components, coatings, liners, plasticized films and single-use articles. SPI said, "when finished articles made therefrom (a) are properly tested under appropriately specified test methods and (b) it is thereby shown that such articles present no reasonable expectation of a transfer of vinyl chloride monomer to foods or food simulating solvents."

Vinyl chloride copolymers covered by the SPI proposed §121.2009 would be: vinyl chloride-vinyl acetate copolymer, vinyl chloride-butadiene-acrylonitrile copolymer, and vinyl chloride-vinylidene chloride copolymer, in addition to polyvinyl chloride.

A similar proposal, submitted by Tenneco Chemicals, would include all vinyl chloride polymer resins in the prior sanction listing. However, for polyvinyl chloride, the firm asked FDA to change each provision "enumerating permitted forms of polyvinyl chloride for food-contact use proposed..." by adding the words "semi-rigid and rigid sheet and blow-molded articles."

SPI argued that FDA should drop its proposed listing of VCM and PVC in the §121.206 listing of substances banned from use in foods. Commenting that the use of a "negative list" is contrary to the "positive list" philosophy of food additive regulation, SPI listed the "following additional untoward and illegal consequences" which would arise from the FDA proposal:

"1. As the law is written, a manufacturer or user of a food additive has the burden of proving its safety and bringing about the promulgation of a proper Food Additive Regulation specifying in a positive way what may be safely used and how. On the other hand, such a party has the right to conclude that a substance such as a packaging material component is not a food additive, in which case the burden of proving such a substance is subject to the Act is upon the government.

"On innumerable occasions the Administration has duly recognized the fact that 'if a food manufacturer or his food packaging supplier(s) has migration data which establishes that there is no reasonable likelihood of migration to food, he need not seek confirmation of his decision from the FDA that the packaging material is not a food additive' (quote from Thomas W. Brown letter Aug. 21, 1970 when Brown was Director of the Office of Compliance in FDA's Bureau of Foods, Pesticides and Product Safety) x x x"

Even more recently, SPI said, a Court of Appeals duly noted that the FDA must be capable of demonstrating that any packaging material which it proposes to seize contains a food additive.

For example, the Society continued, the Court noted that if food placed in a container will be insulated from migration by a barrier "so that contamination cannot reasonably be expected to occur," the container is not a food additive and would not be subject to sanctions under the Act (See FOOD CHEMICAL NEWS, Dec. 8, Page 26).

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If the Section 121.106 language now proposed as regards VCM or PVC is adopted, the statutory definition of "food additive" and the above-cited interpretations will be seriously subverted, the comment said, explaining: "This is because, at best, it will appear that all uses of vinyl chloride homopolymers and copolymers not specifically excepted from the Section's banning impact are prohibited from any use where there is a remote possibility of food contact even if an application were to be of a type where no migration of VCM is sensibly possible, e.g. where vinyl chloride based polymers or copolymers might be a component of a meat truck liner or piece of food processing equipment."

At worst, and yet quite likely as a practical matter, SPI declared, food processors "frightened by such a banning provision could be expected to resist use of any vinyl chloride based end product in their plants for any purpose. We do not believe such a result is intended, nor at all necessary to accomplish the FDA's legitimate objectives

"2. The presently proposed language is additionally anomalous, especially in comparison with the other listings in Section 121.106, because of the excepting clause. In one breath the FDA is bringing to bear the 'negative list' concept and then, in the next, departing from it by setting forth exceptions which are cross-referenced to a set of 'positive list' type regulations, the first of which will be a Prior Sanction Affirmation Regulation (Section 121.20) and the rest of which are likely to be conventional Food Additive Regulations in Subpart F."

Adoption of the proposed amendment to Section 121.106 will unnecessarily distort the basic "positive list" philosophy of food additive regulation generally, and will constitute a dramatic departure from the stated purpose of Section 121.106, SPI said, arguing: "Moreover, the inclusion of the exceptions will derogate from the essential purpose of the Section, i.e. to provide a ready reference as to banned food ingredients, because the exception clauses will indicate that some uses of vinyl chloride based polymers and copolymers are permitted while others are not."

The reader will then be left to look elsewhere or seek specific ad hoc FDA interpretation for guidance on the parameters of the ban and the exceptions, the Society contended.

Urging FDA to withdraw its §121.106 proposal, SPI argued that "instead it should deal with the vinyl chloride polymer and copolymer problem as it has dealt with essentially all other indirect food additive situations; that is by the adoption of 'positive list' type regulations which properly prescribe conditions of safe use, implicitly prohibit uncleared uses, and leave to manufacturers their statutory right to determine when a substance is a food additive subject to the law, and when it is not."

A similar argument advanced by Tonneco noted that the proposed regulations "are based on the erroneous assumption that manufacturers and users of polyvinyl chloride articles intended for food-contact uses are obliged to satisfy FDA that their products are not subject to the agency's authority under the Food, Drug and Cosmetic Act."

"In reality," the firm maintained, "the obligation is FDA's to establish the basis for its jurisdiction."

"No reports cited by the proposal suggest that polyvinyl chloride is unsafe or that, under foreseeable conditions of use as a food packaging material, it is expected

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to become a component of food," Tenneco said. The agency "therefore does not purport to assert regulatory authority over a food package merely because it contains polyvinyl chloride," it added, continuing:

"In a seizure action or other judicial proceeding to establish its enforcement authority over a particular article of polyvinyl chloride intended for food-contact use, FDA would instead be obliged to show that the article contained some other substance (such as VCM) that was likely to migrate to (or was 'reasonably expected to become a component of') food and that the migratory substance was, or would cause food to be, adulterated.

"In each case, FDA would bear the burden of proof as to these issues. If, in a civil proceeding, the agency failed to establish each of these facts by a preponderance of the evidence, a court would determine that the article in question was not subject to FDA's jurisdiction under the Food, Drug, and Cosmetic Act."

FDA is attempting to use the proposed regulations as a means to avoid "seizures or other enforcement actions alleging that particular PVC food-contact materials contained 'poisonous or deleterious' substances" likely to be added to food, Tenneco charged, adding:

"Assuming, for the sake of argument, the appropriateness of this effort to use agency rulemaking power to avoid a series of judicial determinations, whatever mechanism is chosen to establish the agency's authority, the fundamental factual issues underlying FDA assertion of interest and jurisdiction must remain the same. FDA must still meet its obligation to set out facts sufficient to support a conclusion that any particular kind of PVC product is subject to the Act."

Instead, Tenneco commented, the proposal "assumes ... that the burden is on the manufacturer or user of a PVC food-packaging material to establish to FDA's satisfaction that the use of the material may not reasonably be expected to cause VCM to become a component of food."

"In fact," the firm complained, "the preamble suggests that a determination may be made to ban the use of a particular class of products, even though no residual VCM migration into food-simulating solvents can be induced, if the manufacturer or user fails to satisfy FDA that a 'sound theoretical basis' exists for predicting that no migration will occur."

Tenneco cautioned that "this approach, which presumes agency jurisdiction over a particular product in the absence of any factual showing to support it, would be summarily rejected by a district court," saying, "Its application in a rulemaking proceeding is inappropriate and unlawful."

While the data presented in the proposal by FDA may support the agency's claims, Tenneco added, such data are "outmoded and unrepresentative," and "are an insufficient foundation for the assertion of regulatory jurisdiction."

It reported that its studies "affirmatively establish that PVC sheet made by commercially feasible manufacturing methods cannot reasonably be expected to cause vinyl chloride monomer to become a component of food."

Similarly, SPI argued that FDA "cannot prescribe the use of a substance which may not reasonably be expected to become a component of foods," and that "the current state of the industry provides assurance that the intended use of PVC food contact articles may not reasonably be expected to result in vinyl chloride becoming a component of any food."

"Extensive analytical testing, as well as theoretical evaluations relevant to presently available semi-rigid and rigid articles demonstrate there is no reasonable expectation vinyl chloride monomer will become a component of foods as a result of their continued use as intended," SPI insisted.

Pointing to the test results submitted with its comments, the Society said these "are consistent in demonstrating that when the level of vinyl chloride in a vinyl based article is below approximately 1 p.p.m., there is no reasonable expectation that vinyl chloride will become a component of food as a result of the article's employment as a single-use food container."

Data on bottles submitted by Air Products and Chemicals, Ethyl Corporation, Hooker Chemicals' Ruco Division and B. F. Goodrich, showed "no quantifiable levels of vinyl chloride," SPI stated.

Additionally, it suggested, data on sheet and film formulations, submitted by Pantasote Company, Tenneco Chemicals, American Hoechst Corp., Oscar Mayer and Air Products and Chemicals, show no reasonable expectation of vinyl chloride migration to foods.

Test Methodology Called Reliable for VCM Migration

SPI insisted that "the test methodology employed to supply the attached scientific data relating primarily to rigid and semi-rigid food contact articles is exceptionally sensitive by virtue of its built-in gross exaggerations of actual use conditions and may, therefore, be relied upon with confidence to reach conclusions concerning potential VCM migration."

Further, the Society said, "the data supplied in these comments and the appendices, viewed in the light of sound and ultraconservative toxicological projections, are wholly adequate to support regulations which will permit the continued safe use of all vinyl chloride based polymer and copolymer food contact articles meeting the limitations recommended" in SPI's proposed GMP and prior sanction regulations for the vinyl chloride

The Society "submitted that FDA can and should adopt the position that an adequate analytical sensitivity to decide the threshold question of whether a substance is a food

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additive or not is one that is sufficient to assure that no significant risk of harm will result should the method be used and none of the substances be found when exaggerated extraction tests are conducted."

While the "questions of the risk to humans associated with the oral ingestion of vinyl chloride cannot be conclusively assessed at this time," SPI said, FDA is not precluded from "bringing its judgment to bear on the safety of PVC products where it is shown that there is no reasonable expectation of VCM migration to foods."

"Available studies ... clearly indicate that even fairly high levels of vinyl chloride in the diet of test animals were without effect," the comments stated, asserting that "there is reason to believe that VC may not be a carcinogen when animals are exposed to low levels."

"Work now being conducted by Dow Chemical and others," SPI explained, strongly suggests "that low levels of vinyl chloride are metabolized by different routes than high levels."

The Society also referred to data used in Occupational Health and Safety Administration hearings on vinyl chloride exposure of workers, and to estimations based on Mantel-Bryan and other statistical techniques, developed by the National Cancer Institute's Dr. Martin Schneiderman and his co-workers. SPI said these show "that an analytic procedure which would detect approximately 1.3 p.p.m. vinyl chloride in food would be suitable for deciding the determinative question here of whether vinyl chloride may reasonably be expected to become a component of food," commenting:

"In other words, even a relatively crude analytical procedure with an LDL (lower detection limit) of 1.3 parts per million vinyl chloride in food should be sufficient to decide whether or not vinyl chloride could be expected to be a food additive in any particular test situation; in the data actually developed, however, the procedures used are far more refined so that there surely can be no reasonable expectation that vinyl chloride would become a component of food under the conditions of use contemplated for the products tested."

Tenneco referred to work by Dr. Seymour G. Gilbert of the Rutgers Department of Food Science, which, the firm said, "indicates that rigid or semi-rigid PVC contains 'active sites' that tend to adsorb vinyl chloride monomer," elaborating:

"When VCM is present at low concentrations in PVC, these active sites retain the molecules of VCM and prevent their migration to food. Dr. Gilbert's work indicates that the 'break point' for this adsorbing function occurs at residual VCM levels of approximately 1 p.p.m. PVC food packaging materials that contained less than 1 p.p.m. of residual VCM would not release that monomer to food but would retain it instead."

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"Experimental test results, taken together with the work of Dr. Gilbert and others, thus establish that PVC sheet of the kind currently being produced by Tenneco cannot reasonably be expected to cause VCM to become a component of food. Such expectations of non-migration may be assured on a continuing basis by requiring that production samples of food-grade sheet be regularly analyzed and determined to contain no detectable residual VCM according to appropriate test methodology."

As for FDA's proposed interim food additive regulation §121.4009, covering use of PVC in water pipes, "such action should be taken provided it is made clear that the interim rule will be deleted permanently, and not replaced, once FDA is properly satisfied on this subject," SPI stated.

It noted that "indications we have been given (are) that FDA has or soon will receive data from the Environmental Protection Agency noting its conclusion that, after studies of actual potable water systems using methodology of exquisite sensitivity, the use of such systems presents no public problem ..."

Furthermore, the Society said it holds the "position that FDA jurisdiction vis-a-vis potable water piping systems is, at best, questionable," maintaining:

"... this is an area better left to the traditional state and local authorities under their code-making and enforcing powers; the rest of the regulatory field, if there be any, is more properly the province of the ... EPA.

"FDA's projected entry into the intricately complex sphere of water distribution system regulation has no sound statutory base; worst of all, such entry would compel inapt Food Additives Amendment treatment and promulgation of a host of new regulations which would be completely unenforceable."

The Society concluded that the actions it recommended are "amply justified by the voluminous technical data base provided in this filing," which SPI said "would assure public safety while allowing continued marketing of exceptionally useful plastics products, and would otherwise constitute very responsible FDA handling of a problem with careful account having been taken for the public interest, convenience and necessity."

It asked that agency to take the actions "promptly since public concern about PVC products has been highly aroused by continuing publicity on the subject; thus, there exists a true need to alleviate an unnecessary and unreasonable fear which, by its intrinsic nature, is injurious to the public, industry and the regulatory agency."

