

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESEAN, JR.
ROBERT H. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. DEMCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MORRONE
LARRY S. SOLOMON

LAW OFFICES
KELLER AND HECKMAN
1300 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

March 25, 1976

No. 18

TO: All Members of PVC/VCM Mailing Lists

RECEIVED
MAR 29 1976
P.J. JOSEPHANS

Ladies and Gentlemen:

During the past week there have been some developments of interest regarding the vinyl chloride and polyvinyl chloride situation, primarily as regards the pending Food and Drug Administration (FDA) rulemaking proceeding. As a result of informal conferences at the Food and Drug Administration, we should perhaps first advise that FDA is still indicating a target date of "the end of the next quarter" for action of some type. Nevertheless, our feeling is that the target date is not particularly firm since a number of what might best be characterized as internal philosophical differences will require resolution.

In the following paragraphs, our objective will be to bring you up to date once more to the fullest extent possible on the FDA status; as far as the Environmental Protection Agency and the Occupational Safety and Health Administration are concerned, we have no additional hard intelligence to convey.

Late last week Ralph Harding and others in this country were contacted and advised that Dr. John Stafford, who has replaced Dr. Barry Barnes, as Chairman of the CEFIC (European Council of Chemical Manufacturers' Federations) Committee for the Toxicity of Vinyl Chloride would be visiting in this country to tell a number of us about the activities taking place overseas. Rather than burden you with an attempt at summarizing the most worthwhile conversations we, Ralph, and others have had with Dr. Stafford,

BOR 008809

March 25, 1976
Page Two

we are simply enclosing herewith the following documents which we believe will serve to provide you with a "bottom line" on what has taken place:

1. A copy of a generally excellent report prepared by the CEFIC Committee. Despite the covering letter from Mr. Garnett to Mr. Harding with respect to the report, we think it is fair to say that it may now be considered generally available information since the document has been given to the appropriate parties in foreign governments, and we have now transmitted a copy to the Food and Drug Administration.

2. A copy of a letter Ralph Harding has sent to Dr. Louis B. Thomas of the National Institute of Health, National Cancer Institute, strongly urging Dr. Thomas to consider a visit with Dr. Maltoni to obtain the very latest word on the Maltoni toxicology studies. You will note that a copy of Ralph's letter was also sent to Mr. Richard Ronk at the Food and Drug Administration. Information copies will likewise be transmitted to the National Institute of Occupational Safety and Health, and perhaps others.

3. Finally, there is enclosed a copy of a letter we directed to Dick Ronk of the Food and Drug Administration yesterday. As you will see, this letter was employed to transmit the CEFIC report and directed attention to the part thereof which indicates that Dr. Maltoni has thus far seen no liver angiosarcomas at the 3.3 mg/kg dose level. It was necessary for us to indicate in the letter to Mr. Ronk that we differ with some of the discussion

BOR 008810

March 25, 1976
Page Three

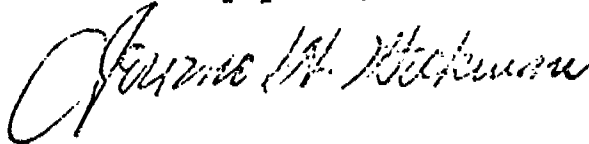
in the CEFIC work, particularly to the extent that it urges the setting of what would amount to finite "tolerances" for VCM migration. Our European contacts understand that we cannot support that position here since this could bring the Delaney Clause into play in a way that we have consistently sought to avoid.

Aside from this activity, we have also been in close touch with the National Sanitation Foundation and our contacts at FDA on the PVC pipe situation. It remains in a state of flux so that we have nothing we care to report at this time. We do want you to know that we are working on a strategy which we hope will bear significant fruit but this is all we are in a position to say at the present time.

* * *

As far as we are aware, the Environmental Protection Agency still plans to take action on its proposed standard by the end of June, although earlier action is possible. With respect to OSHA, we do understand that still more companies have applied for variances with the April 1 effective date almost upon us; should we obtain additional information in this respect, or with regard to somewhat vague "stirrings" on other enforcement questions at OSHA, we will report to you appropriately.

Cordially yours,



Enclosures

BOR 008811

C O P Y

C O P Y

March 24, 1976

Dr. Louis B. Thomas
Chief, Pathological Anatomy Department
Clinical Center
National Institute of Health
Bethesda, Maryland 20014

Dear Dr. Thomas:

I have been told that Professor Cesare Maltoni has informally and orally given further interim findings on his on-going vinyl chloride animal studies to a group of French cancer specialists in early March. Therefore, I would like to recommend that you make contact directly with Professor Maltoni so that we may have the benefit of your analysis of these data.

This letter is addressed to you because of your central role in this matter, and so that the work of your group can be properly extended to include any new data that he makes available to you.

It is my best judgment that this contact should be made through a personal visit to Bologna. During Professor Maltoni's last visit to the United States he indicated on a number of occasions that he did not want to make any more public or written statements on an interim basis. Indeed, he felt it best to complete his studies and then publish a final report before returning to the United States. However, I believe that if you and other qualified pathologists were to call on him, he would share his most current observations with you. A CEFIC report*which we are today giving to the Food and Drug Administration contains some interim observations from Maltoni studies that are more current than anything previously published.

Finally, the Vinyl Chloride and Polyvinyl Chloride Producers Group, which I represent, would prefer that the data be given directly by Professor Maltoni to you. Experience has shown that much more is accomplished when this type of sophisticated program is discussed directly by those who are fully qualified to determine its significance.

If you wish, I will be pleased to help you with appropriate arrangements.

Cordially,

RLH:lj

CC: Professor Cesare Maltoni
Richard Ronk

BOR 008812

*"Vinyl Chloride Toxicity & the Use of PVC for Packaging Foodstuffs" prepared by the European Council of Chemical Manufacturers' Federations (CEFIC)

JOSEPH E. KELLER
JEN ME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESEANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. DEBCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CANOLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MONRONE
LARRY S. SOLOMON

LAW OFFICES
KELLER AND HECKMAN
250 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2100
CABLE ADDRESS "KELMAN"

March 24, 1976

Mr. Richard J. Ronk
Director, Division of Food
and Color Additives
Room 5825, HFF-330
Food and Drug Administration
200 "C" Street, S. W.
Washington, D. C. 20204

Re: Docket No. 75 N-0190--Vinyl
Chloride Polymers in Contact
With Food; Notice of Proposed
Rulemaking, 40 Fed. Reg. 40529,
September 3, 1975.

Dear Mr. Ronk:

In connection with the above-referenced proposed rulemaking, the purpose of this letter is to provide the Food and Drug Administration with relevant additional information which has just been received by us. Thus, enclosed herewith are three copies of a publication entitled "Vinyl Chloride Toxicity and the Use of PVC for Packaging Foodstuffs." The document was prepared by the European Council of Chemical Manufacturers' Federations (CEFIC) Committee for the Toxicity of Vinyl Chloride.

Also enclosed are three copies of a letter just directed to Dr. Louis B. Thomas of the National Cancer Institute by Ralph L. Harding, Jr., President of The Society of the Plastics Industry, Inc. As you will see, this letter indicates that Professor Cesare Maltoni reported further interim findings vis-a-vis his ongoing vinyl chloride animal studies to a group of French cancer specialists early in March.

BOR 008813

Mr. Richard J. Ronk
March 24, 1976
Page Two

With respect to the CEFIC publication, although it is marked "confidential," we have been authorized to transmit copies to the Food and Drug Administration by a CEFIC representative who has given us permission to reproduce and distribute the document. Of particular interest to us, and we suspect perhaps to FDA, is Table 3 which appears in Appendix 3 of the report. This table summarizes Professor Maltoni's ingestion data 84 weeks into his experiment. We, therefore, believe the data is more up to date than that previously made available in any formal way. We are particularly pleased to have noted that, at the 3.3 mg/kg dose level, no liver angiosarcomas have been seen as of this date.

In submitting the CEFIC report, we do wish to emphasize that SPI in no way endorses all of the philosophical or legal concepts and principles presented therein; indeed, we continue to hold to the position that the Delaney clause is wholly inapplicable to the polyvinyl chloride packaging problem in light of the current state of the art in this country. However, we believe that the CEFIC discussion about the assessments of risk associated with low level exposures to vinyl chloride are sound, and provide strong additional support for the position advanced by SPI in its Comments, i.e. that a determination that there is no reasonable expectation of migration of vinyl chloride to food by means of a suitable analytical procedure assures that there will be no risk of harm when such packaging is used.

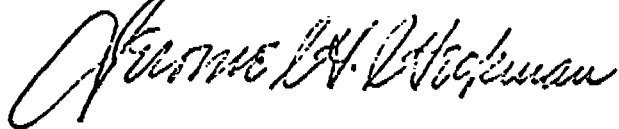
With respect to the information we have heard regarding Professor Maltoni's informal oral reports, you will note that Mr. Harding's letter to Dr. Thomas urges that he consider visiting with Professor Maltoni with a view towards obtaining details from him about the precise status of his activity. It might well be that the Food and Drug Administration should also consider contacting Professor Maltoni to obtain the benefit of the best available toxicological data to guide its deliberations.

BOR 008814

Mr. Richard J. Ronk
March 24, 1976
Page Three

We trust that you will find the information we are providing useful. If there is anything you feel we can do to help arrange for more direct contact between the Food and Drug Administration and appropriate parties overseas, we will be glad to do so. In the meantime, we will continue to transmit to you any additional information we receive.

Cordially yours,

A handwritten signature in cursive script, appearing to read "Jerome B. Hogenman".

Enclosures

BOR 008815

CEFIC

CONSEIL EUROPEEN DES FEDERATIONS
DE L'INDUSTRIE CHIMIQUE

EUROPEAN COUNCIL OF CHEMICAL
MANUFACTURERS' FEDERATIONS

SQUARE MARIE-LOUISE 49
1040 BRUXELLES

Tel.: 02/735.40.80
Telex: FECHIM B 23.167

R: ASG/TB/306a

16th March 1976
Bruxelles, le

Mr. Ralph L. Harding, Jr.
SOCIETY OF THE PLASTICS INDUSTRY INC.
Park Avenue 250
New York, New York 10017
U. S. A.

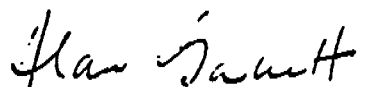
Dear Mr. Harding,

I have pleasure in enclosing copies of a book that we have prepared entitled "Vinyl Chloride Toxicity and the Use of PVC for Packaging Foodstuffs". The book is almost entirely the work of Barry Barnes. It is intended to bring together all the facts concerning the use of poly vinyl chloride food packages and to make an assessment of the risk factors and thus provoke, what we hope will be useful, discussions leading to a better understanding of all the factors involved.

The book has been distributed quite widely in Europe to government authorities, research centres and within industry. It has not been released to the press.

In view of the fact that national governments and the European Commission have copies we would have no objections if you wish to discuss the document with the FDA or any other branch of the US government. As a matter of interest we would like to know if this document is shown to a government department what protection from further publication copyright affords us.

Yours sincerely,



A.S. Garnett

cc: Mr. Heckman

BOR 008816