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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.

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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.

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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, reading "Jerome D. Wickman". The signature is written in dark ink and is positioned below the typed name "Jerome D. Wickman".

Enclosures

SPI-26071

RECEIVED MAR 29 1976

SPI-26072

CEFIC

CONSEIL EUROPEEN DES FEDERATIONS
DE L'INDUSTRIE CHIMIQUE

EUROPEAN COUNCIL OF CHEMICAL
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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.

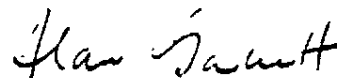
Dear Mr. Harding,

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

SPI-26073