M E M O R A N D U M

Re: Polyvinyl Chloride Plastics and
Vinyl Chloride Monomer Problem

In light of information which has recently reached us, on behalf of The Society of the Plastics Industry, Inc., we are deeply concerned about the type of regulatory approach we understand may now be under consideration relative to polyvinyl chloride plastics food packaging materials. We are fearful that some of the salient facts are not clearly understood and that, unless they are fully taken into account, the plastics industry will be severely adversely affected without any concomitant benefit to the public health, safety or general interest.

Ever since October 1[illegible] when SPI's Comments were submitted in response to [illegible]od and Drug Administration's first proposed rulemak[illegible] polyvinyl chloride and its prior sanctioned status, [illegible] advocated that the prior sanction be reaffirmed but th[illegible]tations be spelled out for the first time to assure t[illegible]ere will be no vinyl monomer (which is not prior sa[illegible]ned) in the food supply.

We continue to urge F[illegible] adopt this approach and recommend strongly that the fo[illegible]g concepts be considered favorably and employed appropri[illegible]y in the redrafting of rulemaking which we now unders[illegible]is taking place:

1. In our view, o[illegible] the most important things the [illegible] and Drug Administration can and should do in dealing with this problem is to employ the Preamble of any proposal to explain carefully that, while vinyl monomer may be a carcinogen */ and is not the subject of a prior sanction as the same is defined in the Food Additives Amendment of 1958, polyvinyl chloride is an

*/ It is conceded that vinyl monomer, a highly volatile gas at room temperature, is a carcinogen when inhaled in high doses over long periods of time. There is no conclusive data to indicate that the same is true as regards ingestion of vinyl monomer; it may not, therefore, be dealt with as having been found to induce cancer after tests "appropriate for the evaluation of the safety of food additives."

VC3863

entirely different ma[illegible]l in the same way that toxic chlor[illegible]e is not sodium chloride (table salt). Polyvinyl [illegible]oride is inert, has been the subject of extensive feeding tests which have shown it to be harmless when ingested and, hence, is very properly the subject [illegible] prior sanction under the Food Addi[illegible]mendment.

2. It is our po[illegible] that the prior sanction should be [illegible]ned even though it could be co[illegible] it need not be the subject [illegible]nce prior sanctioned [illegible]empt from coverage of [illegible]es Amendment. In light [illegible]h has been caused by [illegible]olyvinyl chloride [illegible] since its very nature [illegible]d as a result of [illegible]nyl monomer [illegible] us that re-affirmation of [illegible]l chloride prior sanction [illegible]thwhile. Industry [illegible]e counted upon to suppo[illegible]her than con-test FDA [illegible]is score, provided [illegible]imposed in the process of reaf[illegible]e appropriately designed [illegible]hat the presence of vinyl monomer [illegible]ill not be tolerated.

3. With these [illegible]ations foremost, it is our urgent [illegible]t a prior sanction reaffirmation re[illegible]be proposed and that it (1) indic[illegible] all forms of polyvinyl chlorid[illegible]ging or processing equipment are c[illegible] prior sanctioned and safe provided [illegible]is no detectable monomer [illegible]them using extraction procedure[illegible]easonably exaggerate intende[illegible]ons of use, and (2) that a su[illegible]hod for analyzing extractability be [illegible]h in such a reaffirmation regula[illegible]with regard to

VC3864

the method published, it [illegible] viously
be one that has been sati[illegible]ly
validated and will be rel[illegible]t
practical day-to-day appl[illegible] We
believe that the Food [illegible]min.s-
tration's Staff has deve[illegible]ch a
method which can be in[illegible] in a
reaffirmation prop[illegible]

It should be [illegible] that
any analytical proce[illegible]nite.
detection limit, [illegible] If
the extraction test [illegible]gerates
any possibility of m[illegible] with
this exaggerated exp[illegible]s de-
tected, one is not re[illegible]
det[illegible]sitivity [illegible]ack
of [illegible] but fa[illegible]rated
exposure test assure[illegible]is no
reasonable expectation [illegible]on
under actual intended [illegible]of use.
Such considerations [illegible] the
SPI recommendations [illegible] 15,
1973 "Comments".

4. In the course of [illegible]e
proposal of the type de[illegible]ove,
if the Food and Drug Adm[illegible]on
deems it advisable or [illegible]it
might wish to note that [illegible] is
coincidentally responsive [illegible]o-
called HRG test[illegible]on in th[illegible]action
will assure that no vinyl [illegible]e
monomer enters the food [illegible] More-
over, it might be noted [illegible]g that
the limitations the Food [illegible] Ad-
ministration would be [illegible]ld be
far more severe than tho[illegible]have
already been imposed by [illegible]ational
Safety and Health Adminis[illegible](OSHA)
in circumstances where exp[illegible]o vinyl
chloride monomer is not a[illegible] con-
ceptual possibility, but [illegible]ute
certainty. The OSHA Vinyl [illegible] Standard
permits worker exposure of [illegible] part
per million over an eight-h[illegible]ay for

every working day. This is roughly equivalent to permitting 10 ppm of vinyl chloride in the total diet to be ingested daily, if such were possible, which it is obviously not. It is also interesting to note that the Health Research Group participated fully in the OSHA proceedings which led to the adoption of its Standard. HRG did not appeal the OSHA decision as industry did. In fact, HRG spokesmen were believed to have been pleased as being of the opinion that a significant victory had been attained, large part at their instance, in the case.

It would appear to us that the Food and Drug Administration should move in accordance with the principles outlined above and utilize such of the information as is provided in whatever way it deems fit. There are several motivating or otherwise pungent matters which we feel compelled to draw to your attention:

1. The uncertainty as to the status of polyvinylchloride and contact material, and the confusion it with vinyl monomer, has already created unnecessary and very adverse concern in the minds of the public and the food processor customers of the plastics industry. Any formal proceeding which, though recognized as only a procedure, adds to the unfavorable climate will undoubtedly cause grossly unjustifiable damage vis-a-vis the public's sense of security about the food supply.

2. It is generally known that the industry is now supplying polyvinyl chloride resins and compounds to its customers which differ significantly from the basic materials that were in the marketplace at the time the HRG referenced extraction data was submitted. The availability and use of

these new materials can be documented. Use of them will assure there can be no reasonable expectation that polyvinyl chloride packaging materials will lead to vinyl monomer becoming a component of foods, or will be ingested.

We believe that many leading resin and compound supplying companies have already advised the Food and Drug Administration on an individual basis as to the changes that have been made in their food packaging grade products to provide this type of assurance. If more data is needed, however, we can ask that it be supplied and would urge that the Food and Drug Administration receive the same before it makes any precipitous action that would injure the industry's reputation irreparably.

Jo[illegible]. Heckman
Ka[illegible]nd Heckman

Gene[illegible] Counsel for
[illegible]ociety of the
[illegible]ics Industry, Inc.