U. S. INDUSTRIAL CHEMICALS CO.

DIVISION OF NATIONAL DISTILLERS AND CHEMICAL CORPORATION

POLYMER SERVICE LABORATORY • TUSCOLA, ILLINOIS 61953

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Mr. Jerome H. Heckman
Law Offices
Keller and Heckman
1712 N Street, N. W.
Washington, D. C. 20036

Dear Jerry:

The following are our comments on the "Procedural Regulations" published in the August 8, 1967 Federal Register.

As discussed at our meeting on August 20 in Section 121.50 a) (pg 11443) we do not agree with the inference that FDA is competent to rule on the qualifications of the scientists.

In Section 121.50 (pg 11444) I, 5 Toxicology this paragraph is not clear as to "no effect levels". The last sentence is particularly unclear as to what is virtual lack of migration.

In Section 121.50 (pg 11444), II, 2 Indirect Additives, iii if a catalyst is fully consumed in a polymer reaction (no residue) then why is it necessary to list it at all?

In Section 121.50 (pg 11445) II, c Indirect Additives, if a packaging material (in our case a polyolefin) is by definition an indirect additive what can we say about the "intended effect" on the food when there is none intended at all? We've been particularly annoyed at this request by FDA in filing petitions for additives in polyolefin. We've explained the intended technical effect was for the packaging material and not for the food, etc. It seems almost ridiculous to explain it.

In Section 121.50 (pg 11445) B, 2 Indirect Additives in packaging materials such as polyolefins the individual foods or classes of foods may not be known when a general purpose film resin is petitioned for. This has been the case when petitioning for certain processing additives in the polyolefin resin the end application is meant to be for general packaging including food. Must we then list all classes of foods possible? Under what simulated food xtraction conditions can one predict? If we use one specific food and extraction

condition as an example of the possible packaging use, are we limited then to the specific example. This is where, I believe, the FDA philosophy surrounding indirect additives is impractical as is the case in the above mentioned comment on "intended effect."

Jerry, the above may be redundant since these points were discussed at our August 20 meeting and were the subject of some of the authors in the ACS papers last year in New York. However, we wanted to go on record as expressing our opinion on the procedural regulations which FDA has chosen to apply almost more stringently to indirect additives and specifically packaging materials than to direct food additives.

Sincerely yours,

D W Pugh

D. W. Pugh

DWP:mb