May 23, 1969

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Dear Jerry:

The following merely points up our interpretation of the proposed §121.2500 (d)(5) and is not intended to provoke controversy. It may, nevertheless, suggest possible points worthy of discussion at our next meeting.

As we read the opening paragraph of subsection (d)(5), substances which fail the heavy metals test or which are known to be toxic at diet feeding levels of 40 ppm or less are not acceptable under this regulation. Presumably, if the material is not known to be toxic at stated level there is no need to demonstrate lack of toxicity at higher level. However, if any demonstration of lack of carcinogenicity is a requirement, chronic feeding studies may still be needed.

With respect to sub-subpar. (i) of the proposed regulation, we agree that actual analysis of food would involve great difficulty and the 0.05 ppm tolerance is of little value if 100% migration is assumed. Therefore, only the question of what constitutes "appropriate extraction studies" remains. While this is certainly less difficult than with food, I can visualize substantial difficulty in analyses for many organic migrants even with use of simulated solvents, because frequently several components migrate to a greater or lesser degree. More on this below.

In (ii), free oil on finished food-contact article is prohibited, except where otherwise permitted. To my limited knowledge, the only place where surface lubricants are permitted is on metallic surfaces in §121.2531. However, I think it is

possible, if not probable, that so-called "internal lubricants" in plastics may migrate to surface and yield very thin oily films on the surface. Thus, as I interpret this paragraph, if the lubricant is permitted by other regulations it is acceptable here, but any new substance that may "bleed" at the surface is not acceptable.

With respect to (iii), I personally believe that the repeated use surface should be cleansed with a solvent simulating the type of food to be used in the container.

In (v), does this mean that only general provisions of §121.2520 must be complied with or that substance must be listed in §121.2520 (c)(5)? Also, is this not the time to eliminate §121.2520 or to delete the listings, excepting those known to be toxic at the 40 ppm level, e.g., sodium fluoride.

As with the octyl tin regulation, analytical difficulties may be encountered in determining whether additive is less than 0.05 ppm in food or even in simulating solvents. Since the total extractable from many, if not most, food wrappings is greater than that equivalent to 0.05 ppm in food, the extraction residues must be analyzed for the additive under study and this may not be easy. Also, unless FDA agrees to a standard ratio of volume (or weight) to surface area (e.g. 10 ml/sq.in.), package size must be considered. Finally, thickness of food contact material will affect migration. Presumably, thickness could be specified in same manner as volume to surface area ratio but if thick film is specified, thin films usually used, will suffer. In short, my discussion here questions mathematics to be used with any simulated solvents demonstration.

I find FDA proposal quite a bit removed from Jack Frawley's idea.

Very truly yours,

Original Signed
W. A. Knapp

W. A. Knapp
Consultant-Toxicology

WAK:dmk
cc: Mr. Robert M. Mill r, Hercules, Inc.Dela.