d1 FDA - Aroclor 5460

Monsanto

FROM (NAME & LOCATION) St. Louis

DATE October 28, 1970

CC H. S. Bergen - HBERG
W. B. Papageorge - WPAPA
J. E. Springgate - JSPRI

SUBJECT

REFERENCE

TO : Paul Graham
PGRAH

This confirms our discussion of yesterday, in which you asked me for my opinion as to the likelihood of the FDA approving Aroclor 5460 as a component of an adhesive for food packaging.

In my opinion our chances of getting such an approval are extremely slight (certainly under 25%). My reasons for this statement are the following:

1) No matter what posture we take the FDA is bound to consider chlorinated terphenyls as a near relative of chlorinated biphenyls. I do not think they will lay themselves open to an attack because of their approval of a compound which in the public mind is practically the same as a PCB.

~~MUT~~
PCB

There is a great difference between a government agency allowing the use of a product that they may have some misgivings about and that same agency giving active approval to a compound, which is what we would have to ask.

2) At present, we do not have the extent of toxicity the FDA would demand nor the ecological significance of the product that the Department of Fish and Wildlife might require. We have only 90-day testing on rats and chickens. I feel sure the FDA will require, at the very least, 90 days in dogs. They might very well demand rat reproduction studies and even longer dog and rat feeding studies.

We do not have complete biodegradability studies on 5460, nor do we possess subacute fish toxicity studies. I understand the former is underway.

It is my feeling that the FDA, whether they express it or not, will be adamant about the approval of any chlorinated biphenyl or terphenyl for food use. I can't prove this but certainly if I were in their shoes I would do the same. Thus, I feel we will be

DSW 552312

up against roadblocks all along the way and the amount of these could be endless. I think the FDA realizes that once mention of the filing of a petition for the use of a chlorinated terphenyl in food packaging is made that agency would be subject to a barrage of action from various conservationists and Nader-like groups. I can't see them getting themselves into that spot.

I can see no inconsistency between our action of not actively seeking FDA approval and the announced company policy of selling 5460 in areas outside of food use. As I said, one requires government approval and the other requires no outside government disapproval. Politically, it appears to me there is a world of difference between these two conditions.

R. Emmet Kelly, M. D.

REK/ln

DSW 552313

STLCOPCB4090730