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September 1, 1972

Dr. Karl A. Hochschwender
American Hoechst Corporation
Route 202-206 North, Bridgewater
P. O. Box 2500
Somerville, New Jersey 08876

Re: FDA Proposed Rule Making Regarding Environmental Impact Statements (37 Fed. Reg. No. 134, page 13636 et. seq.); Nelson Bills (S.76 and S.3163 Hearings)

Dear Karl:

The purposes of this letter are (1) to follow up on that portion of our July 14, 1972 letter relating to the referenced FDA rule making proceeding, and (2) to at least advise you and the others on our Food, Drug and Cosmetic Packaging Materials Committee about the Hearings Senator Nelson is now expected to hold soon relative to pending legislation which could broaden the kind of testing and clearance requirements already proven so burdensome under the Food Additives Amendment of 1958.

Taking the Environmental Impact Statement matter first, not unexpectedly, we received only one formal Comment from a member of our Committee and that came in the form of a very welcome letter from George Richter who was good enough to supply us with Comments on the proposal Rohm & Haas decided to file directly with FDA. Under the circumstances, we decided to forego the filing of Comments on SPI's behalf. This decision was in keeping with the obervation I made in the July 14 letter to the following effect:

> "Frankly, I have some doubt as to whether any meaningful Comments can be submitted on this proposal in

SEP 5 1972

> light of the fact that it pretty much amounts to an FDA move to quell consumer interest criticism of its alleged failure to comply with the National Environmental Policy Act. Furthermore, our immediate reaction is that there is little that is subject to valid criticism in the proposal."

I still feel that the Food and Drug Administration really has no choice other than to indicate it may require Environmental Impact Statements in appropriate circumstances since another governing Statute is involved. For your information, however, we thought we would supply each member of the Committee with a reproduction of George Richter's Comments. Obviously, and as I have now advised George during a telephone conversation, we are in sympathy with his objectives but have serious doubt that his proposal will be accommodated. We agree that the Food Additives Amendment should not be used as a means for opening broad environmental impact questions since this was never intended by its authors. On the other hand, there can be no question but that the National Environmental Policy Act was designed to force all of the Agencies to superimpose its requirements on existing statutory law.

This being the case, we have little doubt but that FDA will ultimately finalize its proposal in some form. Moreover, our suspicion is that this action is likely to affect indirect additives even more than direct additives because of the general controversy over the solid waste problem. Indeed, my own feeling is that FDA will reluctantly be thrust into the midst of the solid waste debacle because it does have the power to regulate indirect additives. This is why I feel there is little chance that it will exempt indirect additives from the Environmental Impact Statement concept.

About the only note of optimism that can be mentioned in this connection is the fact that perhaps it will be somewhat better if a petitioner is

required to submit the basic data for an Environmental Impact Statement openly, as FDA has proposed, than if the Agency were required to prepare such Statements on its own (at least in theory); solicited the data necessary from the petitioner, as would be the only practical course of action open to it; and then both the Agency and the petitioner were subjected to demagogic type criticism for cooperating.

Unfortunately, in connection with the PVC liquor bottle question with which many of you are familiar, the Bureau of Alcohol, Tobacco and Firearms and SPI have been criticized for working together. Those who have voiced the criticism have made it seem as if there was something evil about our supplying necessary and requested information. Obviously, at least this psychological disadvantage will not have to be suffered if and when the FDA proposal becomes effective.

Finally, while writing to report to you on this matter, we thought we would take this opportunity to let everyone know that Senator Gaylord Nelson has now scheduled a three day Hearing of the Select Committee on Nutrition and Human Needs of the Senate to consider his Bills, and others, that could impose even more stringent food additives controls, i.e. (1) the extension of the Delaney clause so that proof of no adverse mutagenicity, or teratological possibilities, as well as no known carcinogenicity, would have to precede clearance of all food additives, and (2) the outright abolition of the entire "generally recognized as safe (GRAS)" concept so that all present GRAS (and probably "prior sanctioned") substances could presumably have to be cleared by new Petitions and Food Additive Regulations.

We doubt that the Nelson Hearings will lead to any immediate new legislation but they could provide a forum for an interesting debate about the Delaney clause in general. We would therefore recommend that all interested parties consider staying abreast of what takes place when the Hearings are

held from September 18 to September 20. I am sure that Food Chemical News will be covering the proceedings. If anything of direct interest develops, we will also report to you appropriately.

If you have questions about any of the matters covered in this letter, please do not hesitate to let me know.

Cordially yours,

Jerome D. Stockman

Enclosure
cc: SPI Food, Drug and Cosmetic Packaging Materials Committee

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ROHM AND HAAS COMPANY

August 14, 1972

Jerome H. Heckman, Esq.
Keller and Heckman
1150 17th Street, N. W.
Suite 1000
Washington, D. C. 20036

Dear Jerry:

For your information, enclosed is a letter to the Hearing Clerk regarding the environmental impact statement amendment recently proposed by the FDA in which we request that an exception be made for petitions concerned with Subpart F of the food additive regulations. There may be little chance of obtaining favorable action, but we feel that there is nothing to be lost in expressing our objection. If you can think of other arguments, or in any case, you may wish to consider raising a similar objection on behalf of SPI.

Cordially,

George

G. A. Richter, Jr.

GAR:jm
Enc.

August 11, 1972

Hearing Clerk
Department of Health, Education and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Md. 30852

Sir:

Re: Proposed Amendment of Title 21, Chapter I by Addition of New Part 6

The purpose of this letter is 1) to express objection to the requirement in the subject proposal that environmental impact analysis reports be submitted to the Food and Drug Administration as support for petitions to clear indirect food additives under Subpart F of the food additive regulations and 2) to recommend a modification of the proposal which is consistent with this objection. Our reasons for this action are as follows:

1. Subpart F of the food additive regulations is concerned with food additives resulting from contact with containers or equipment. There is no intention to add substances to food. Therefore it can be reasonably assumed that inadvertent additions (e.g., as a result of migration from packaging materials) would be insignificant with respect to environmental impact.

2. It is extremely unlikely that a product being considered for use in contact with food would be manufactured only for uses which are subject to the food additive regulations. It can safely be assumed that components of packaging materials would be manufactured for uses other than food-contact regardless of whether or not such components become cleared under a food additive regulation. Thus, the impact on the environment resulting from the manufacture of a potential indirect food additive would not be significantly affected by its clearance under a food additive regulation in Subpart F.

3. The only reasonable question of safety relating to the use of an indirect additive is the toxicological effect on our food supply. Under existing procedures, the toxicological risk from demonstrated migration of each food additive to the food supply must be carefully documented and considered before a petition for a regulation or amendment under Subpart F of the food additive regulations is promulgated.

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The proposed amendment includes in paragraph (c) of Section 6.1 the following statement

"An environmental impact statement will not be required for amendments to existing regulations and approvals of supplements to existing approvals unless the change is substantial."

In view of this statement and of the arguments presented above, we contend that neither new regulations nor amendments to existing regulations under Subpart F of 21 CFR Part 121 are reasonably expected to cause significant environmental impact. We therefore request that the proposed procedural amendment be amended as follows:

a) Add to the list of agency actions for which environmental impact statements are not required (under paragraph (d) of Section 6.1) an item which reads " ssuance or amendment of food additive regulations under 21 CFR Part 121 Subpart F."

b) Modify subparagraph (b) (11) of Section 6.1 to read "Approval of food additive petitions except for new regulations or amendments to existing regulations under 21 CFR Part 121 Subpart F."

c) In Part 121, modify item H under paragraph (c) of Section 121.51 to read "Except for petitions for regulations or amendments under Subpart F, the petitioner is required to submit an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the food additive pursuant to Section 6.1 of this chapter."

We feel strongly that the above modification of the proposed procedural amendment would be in the public interest since it would eliminate unnecessary and meaningless effort on the part of industry and government without creating a threat to the environment.

cc: Jerome H. Heckman, Esq.
Dr. Karl A. Hochschwender

Very truly yours,

GAR

G. A. Richter, Jr.
Administrative Assistant,
Government Relations

GAR:jm