

DEC 26 1972

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December 20, 1972

TO: All Members of the SPI Food,
Drug and Cosmetic Packaging
Materials Committee

RE: Environmental Impact State-
ments Problem; Phthalate
Matters

Gentlemen:

Two items came up just after our December 15 meeting, one of which I thought should be brought to your attention as promptly as possible. Accordingly, I am enclosing, with the kind permission of the editors, a reproduction of page 17 of the Food Chemical News issue dated December 18, 1972. The marked paragraph refers to a pending action reported by Dr. Fred J. Kingma, Deputy Director of the Bureau of Veterinary Medicine, confirming that the Food and Drug Administration will not approve the use of copper in swine feed to promote growth and improve feed efficiency because of the anticipated possible adverse environmental effect of such an approval.

Those of you who attended the meeting know that we discussed in some detail some of the problems that could be anticipated when the Food and Drug Administration fully implements its obligations under the National Environmental Policy Act of 1969 with regard to assessing the possibility of adverse environmental effects due to its official actions. The item which we have enclosed represents a decision by the Bureau of Medicine to reject a proposal, originally embodied in a food additive petition, not on the grounds that the "food additive" involved is unsafe or ineffective, but rather because of the fear of adverse environmental effects expressed in comments filed by the U.S. Department of Agriculture and the Environmental Protection Agency. This is the first case that we are aware of where this

ASI-PR 0001218

Page Two

Completely unrelated to the foregoing, is a letter which we received from Dr. Robert J. Rubin, Johns Hopkins University School of Hygiene and Public Health, regarding his work with radio-labeled phthalate. The note speaks for itself, and we are taking this opportunity to transmit copies to you for your general information. The conference, to which Dr. Rubin makes reference, is the same conference on phthalates which was reported upon at the recent meeting. The paper in the New England Journal of Medicine, however, is new to us, and we are happy to bring it to your attention in this way.

Cordially yours,

Frederic W. L. G. G. G.

Called Fred Hall - Found his car in yard
and saw 4000 for fingers stopped in car
I - inside eye took 11/73

"In these respects, the consumption of meat by man from selenium-fed animals would result in an increased daily human intake of selenium. From the overall point of human nutrition this is probably desirable, although we presently lack direct evidence in humans.

"If selenium is carcinogenic, supplementation of the human diet is not permissible. If it is clearly shown, however, that malignant disease does not arise in the absence of hepatic injury and regeneration, then one can take the position that sub-hepatotoxic doses of selenium are not associated with cancer, i.e., we have some understanding of the dose-effect relationship and knowledge of those circumstances under which selenium is not associated with cancer."

In another portion of his report on BVM activities, Wingma noted that FDA is holding up any decision on furazolidone and furaltadone pending validation of analytical methodology for the drugs at 0.2 p.p.b. in milk and 2 p.p.b. in other tissues (See FOOD CHEMICAL NEWS, Oct. 15, Page 40; and Nov. 20, Page 16).

He also noted that BVM was forced to reject approval of use of up to 250 p.p.m. copper because review required by the National Environmental Policy Act, as indicated in opinions submitted by the Department of Agriculture and the Environmental Protection Agency, made it all but impossible to give FDA's concurrence (See FOOD CHEMICAL NEWS, Sept. 11, Page 17).

CASE FOR BROAD FDA DISCRETION STATED BY HUTT

The Food and Drug Administration can use any innovative approaches for assuring compliance with the Federal Food, Drug and Cosmetic Act that is not specifically prohibited by Congress, FDA General Counsel Peter Barton Hutt stated at last week's annual FDA-Food and Drug Law Institute meeting in Washington.

Hutt's statement of his "philosophy of regulation" and its justification was immediately followed by a rebuttal. H. Thomas Austern, of the Washington law firm of Covington & Burling, took sharp issue with the FDA attorney. Austern had been furnished the FDA-er's text in advance by Hutt, who served his apprenticeship at Covington & Burling, at which Austern is considered the dean of food and drug lawyers.

Conceding that his "interpretation of the Act is not universally accepted," Hutt summed up his major point, as follows:

" . . . The fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the FDA exerting initiative and leadership in the public interest. Except where expressly prohibited, I believe the FDA is

ASI-PR 0001220

THE JOHNS HOPKINS UNIVERSITY

SCHOOL OF HYGIENE AND PUBLIC HEALTH

DEPARTMENT OF ENVIRONMENTAL MEDICINE

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December 14, 1972

Please Reply to Underigned

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

Dear Jerry:

Just a brief note to bring you up to date on some of our recent work with the radio-labelled phthalate. We have now completed our studies on the absorption, distribution, and excretion of DEHP. We presented that work at the recent conference sponsored by the National Institute of Environmental Health Sciences in September 1972.

The paper as well as the proceedings of the conference will be published in the January 1973 issue of Environmental Health Perspectives. You should be able to get a copy of the issue by writing to Dr. David Pall, Director of the National Institute of Environmental Health Sciences, Research Triangle, Raleigh, North Carolina. In any event, as soon as I get reprints of our three articles from that conference I shall forward them to you.

Incidentally, I might also bring to your attention our paper that appeared in the November 30, 1972 issue of the New England Journal of Medicine. Unfortunately, I don't have reprints of the paper yet, but I trust you will not have any great problem in getting a copy from the journal.

Thank you once again for your continuing interest.

Sincerely yours,

Robert J. Rubin, Ph.D.
Associate Professor of
Environmental Medicine

RJR:mm

ASI-PR 0001221