UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 20 1985

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Mr. Thomas W. Brunner
Piper & Marbury
888 Sixteenth Street, N.W.
Washington, D.C. 20006

Dear Mr. Brunner:

I am responding on behalf of the Agency to the correspondence and information which you recently submitted regarding the applicability of the "food and feed" requirements of the Environmental Protection Agency's (EPA's) polychlorinated biphenyls (PCBs) regulations to the manufacturers of teabags and other food-contact filter papers.

In your correspondence on behalf of the American Paper Institute (API), you vigorously state the API's contention that the entire sector of the paper industry engaged in the manufacture of these "food-contact" papers is entitled to a categorical exemption from the "food and feed" provisions set forth at 40 CFR §761.30(a)(1)(i). Your letter asserts that such a categorical exemption is in order because the Agency explicitly excluded these manufacturers from the rule when it determined that "food" did not include "indirect additives" as regulated by the Food and Drug Administration (FDA).

The Agency agrees with the premise that on the whole, the manufacturing of food-contact filter papers and teabag papers does not pose a significant "exposure risk to food or feed." For that reason, the Agency is confident that the great majority of the manufacturers who might produce these papers will not be subject to the rule's requirements.

Indeed, the circumstances of these filter paper manufacturers are similar in many respects to those encountered in connection with the manufacture of food packaging materials, and basic fairness dictates that they be treated similarly. So, the Agency has determined that the manufacturers of these food contact filter papers are not "food and feed" facilities unless tea or other food products are actually present at the manufacturing site. For example, if a facility were to convert rolled paper to teabags, and then introduce tea to the paper product, such a facility would be subject to the rule's requirements.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Please be advised, however, that this result follows from the application of EPA's previously stated analysis of the factors which should be considered in evaluating an exposure risk to food or feed. In short, these facilities are exempt because EPA does not consider there to be a "potential pathway" to food or feed unless food or feed is located at the facility. See Statement of General Policy, 48 FR 7172, February 18, 1983.

As for those facilities, if any, at which tea or other food products are located, these manufacturers must conduct an individual evaluation of the circumstances of each PCB item's location. If, after considering the PCB item's location and any relevant factors, contact between PCBs and food is reasonably possible, that facility would be subject to the rule. 48 FR 7172.

It is important to note that in making this determination, the Agency rejects the assertion that all facilities manufacturing food-contact filter papers are exempt because such food-contact articles are regulated as "indirect additives" by the FDA. This assertion is not valid.

Our research on this point discloses that the FDA would not consider these products to be "indirect additives."

It is true that substances regulated by the FDA as "indirect additives" (21 CFR part 174 et seq.) are generally described with reference to various articles which are in contact with food. Significantly, however, the FDA treats only the substance which actually migrates into food as the "indirect additive;" the packaging material, adhesive, etc., from which the substance migrates is merely considered to be the "food-contact article" associated with the migratory substance. So, a category of paper contact articles--such as teabags or coffee filters--would not be regulated in any event as "indirect additives."

Moreover, our research discloses that the concept of an "indirect additive" involves more than the contamination of food by the migration of a substance through a food-contact article. Rather, an "indirect additive" as regulated by the FDA, is a migratory substance which itself has some intended function or effect in the contact article, although it is not intended to accomplish any effect in food. This fundamental attribute of an "indirect additive" appears in the FDA definition of "food additives," 21 CFR §170.3(e), in the general provisions defining what are "good manufacturing practices" with respect to "indirect additives," 21 CFR §174.5(a)(1), and in statements by the FDA. For example, in the course of FDA rulemaking which imposed "indirect" additive controls on lead migrating from solder seals in tin cans, the FDA made it clear that "indirect additive" status attaches only to those migratory substances which satisfy the requirement of functionality in the food contact article. 44 FR 51233 at 51239. In this regard, it is significant that where PCBs in food packaging materials are concerned, the FDA regulates

these PCBS as an "unavoidable poisonous or deleterious substance" (21 CFR §109.30) rather than as an indirect additive under 21 CFR part 176.

Clearly, any contamination by PCBs which would result from a leaking PCB item in a filter paper manufacturing facility would not arise from any intended function of the PCBs in the paper article. Indeed, cases dealing with similar circumstances negate the assertion that any such contaminant would be a "food additive" at all. Instead, these cases characterize the contaminant as an "accidental additive." Burke Pest Control, Inc. v Joseph Schlitz Brewery Co., 438 So.2d 95 (Fla. App 1983); United States v Vita Food Products of Illinois, Inc, 356 F. Supp. 1213 (N.D. Ill. 1973), reversed on other grounds, 502 F 2d 715 (7th Cir. 1974).

Therefore, the exempt status of filter paper manufacturers arises from the "potential pathway" test stated in the rule, and is conditioned upon the absence of food from the facility. "Indirect additives" play no part in the determination.

Should you have any questions on this matter, please do not hesitate to contact this office.

Sincerely,

/s/ Signed

Suzanne Pudzinski, Chief
Chemical Regulation Branch