(AF 4-408)

July 20, 1966

TO

FROM

SUBJEC

Mr. Richard E. Rea, Legal Department
E. I. du Pont de Nemours & Co., Inc.
7056 du Pont Building
Wilmington, Delaware 19898

Re: Food Additive Petition No 5B1747

Dear Mr. Rea:

We have your letter of June 21, 1966, supplementing Food Additive Petition No. 5B1747.

Our consideration of the petition as supplemented reveals the need for the following data:

1. A fluorine range for the additive, suitable for identification purposes, together with a method of analysis for determining the fluorine range.

2. The individual values used to determine the blank value reported for extraction on the board not treated with (b) (4) [redacted]

3. An end test suitable for limiting migration of the additive to food.

Sincerely yours,

Willard G. Orr
Petitions Control Branch
Bureau of Science

cc: PCB FSA DTE ACR

WGOrr:mmm 7/13/66
7/20/66

Initialed:JMcLaughlin 7/19/66
Phone conc.:WGMcreary 7/19/66

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OPTIONAL FORM NO. 10
MAY 1962 EDITION
GSA FPMR (41 CFR) 101-11.6

UNITED STATES GOVERNMENT

Memorandum

TO : Petitions Control Branch

DATE: July 21, 1966

FROM : Drs. K. P. Misra & J. McLaughlin, Jr.
Division of Toxicological Evaluation
Petitions Review Branch

SUBJECT: Amend regulation 121.2526 (Components of paper and paperboard in contact with aqueous and fatty foods) to include mono-, and bis-(1-H, 1H, 2H, 2H-per fluoroalkyl) phosphates-diethanolamine salts as an optional component of paper and paperboard.

FOOD ADDITIVL PETITION NO. 5B1747
(Supplement to Final Evaluation)

E. I. DuPont de Nemours & Company
Wilmington, Delaware
(AF 4-408)

The revised submission (June 21, 1966) restricts the use of (b) (4) to 0.25% by weight of paper. It leads FSA to suggest (FSA memo to PCB dated June 27, 1966) a migration of 0.2 ppm to aqueous food and nil to fatty food. This would be essentially in the form of (b) (4) because of its stability in strong mineral acids and alkalies. The use limitation should further restrict for contact with foods under conditions of use of E, F, G and H of Table 2 regulation 121.2514.

In support of higher "no effect" level for (b) (4) (TE memo to PCB dated Feb. 3, 1966), the petitioner advances a supplementary point. The diethanol amine content of (b) (4) is about 16-17%. The "no effect" level from Mellon Institute's report is between 20 to 90 mg/kgm in rats for diethanolamine (suggested). The effect level is 90 mg/kgm. At a level of intake of 100 ppm of (b) (4) the intake of diethanolamine would constitute about 10 mg/kg, and consequently at 1000 ppm of Zonyl RP it would be about 100 mg/kgm. Thus, the slightly enlarged liver effect observed at 500-1000 ppm of (b) (4) could be due to a combined effect of the diethanolamine and flurocarbon moieties of (b) (4)

Evaluation: We can state that the "no effect" level is less than 1000 ppm of (b) (4) but more than 100 ppm. With the proposed use restrictions (lowered use level, and restricted food contact use conditions) we consider the use of (b) (4) safe.

CONCLUSION: The use of (b) (4) as revised and proposed (FSA memo to PCB dated June 27, 1966) is safe. The basis of safety rests on the expected level of migration (0.2 ppm.) and toxicity data (Two 90-day studies in both rat and dog) on (b) (4) We recommend a promulgation of a regulation, only when FSA's requirements (FSA memo to PCB dated June 27, 1966) are met in support of this petition.

INIT: HBlumenthal 7/29/66

cc: TE, FSA, FAP No. 5B1747

KPMisra&JMcLaughlin, Jr.:smr 7-21-66

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