

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P. C.

700 THIRTEENTH STREET, N. W.
SUITE 1200
WASHINGTON, D. C. 20005

TELEPHONE
(202) 737-5600
FACSIMILE
(202) 737-9329

October 15, 1993

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
ROBERT T. ANGAROLA
STEPHEN H. MCNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
FRANK J. SASINOWSKI
DIANE B. MCCOLL
A. WES SIEGNER, JR.
SAMIA N. RODRIGUEZ
MARY BETH NERAAS
BRIAN L. PENOLETON
SUZAN ONEL
ALAN G. MINSK
GAIL P. MIDDLEKAUFF
KENNETH A. OLSEN

C. JOSEPH STELLER
OF COUNSEL

HYMAN, PHELPS & MCNAMARA
2603 MAIN STREET
SUITE 1066
IRVINE, CALIFORNIA 92714
TELEPHONE (714) 553-7400
FACSIMILE (714) 553-7433

DIRECT DIAL (202) 737-

4289

66-715-1000
RECEIVED
OCT 20 1993
R. HINDERER

Mary E. Schulz, Esq.
Senior Environmental Counsel
The BFGoodrich Company
Law Department
GEON Division
6100 Oak Tree Boulevard
Independence, Ohio 44131

Dear Mary:

On October 12, 1993, FDA finally published its proposed "threshold of regulation" policy for food packaging materials. 58 Fed. Reg. 52719. A copy of the Federal Register notice is enclosed for your review. The proposal closely follows the existing system for obtaining "no object" letters from FDA.

Because of the Delaney Clause, the agency proposes to apply the threshold of regulation only to noncarcinogens. Materials with trace amounts of carcinogenic impurities would be eligible for the threshold of regulation only if two criteria are met: (1) the TD₅₀ (the feeding dose that causes cancer in 50 percent of test animals) for the impurity is less than 6.25 mg per kg body weight per day, and (2) the chemical structure of the substance containing the impurity does not suggest potential carcinogenicity. This is similar to the "constituents" rationale used by FDA to approve color additives that are not themselves carcinogens, but that contain trace amounts of known carcinogenic impurities. See 58 Fed. Reg. at 52723; Scott v. FDA, 728 F.2d 322 (6th Cir. 1984).

FDA proposes a threshold limit of "dietary concentrations at or below 0.5 ppb, corresponding to dietary exposure levels at or below 1.5 micrograms/person/day." 58 Fed. Reg. at 52722. For currently-approved direct food additives, the agency would apply a dietary exposure limit of "less than 1 percent of the acceptable daily intake as determined by the safety data in the Food and Drug Administration files." 58 Fed. Reg. at 52723.

RECEIVED

OCT 19 1993

BFG52092

21739001

Mary E. Schulz, Esq.
October 15, 1993
Page 2

HYMAN, PHELPS & MCNAMARA, P.C.

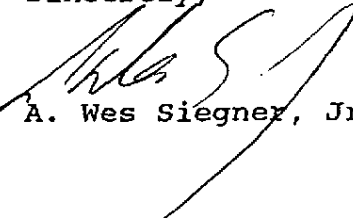
In addition to formalizing the data for requesting exemption from regulation as a food additive, the proposed rule provides that FDA may on its own initiative reconsider its decision and withdraw an existing exemption. 58 Fed. Reg. at 52725.

Perhaps most importantly, FDA proposes to make available to the public a list of the substances exempted from regulation as food additives. The list will disclose the name of the company that requested the exemption, the chemical name of substance (no reference to the trade name), and the specific use for which an exemption has been granted, including any limits on such use. The environmental assessment submitted with the exemption request will also be placed on public display. 58 Fed. Reg. at 52724.

I recommend that BFGoodrich review the proposal to determine if any of the provisions are likely to present difficulties for any of the company's products. If so, BFGoodrich should consider submitting comments to the agency. The deadline for public comment is December 13, 1993.

Best regards.

Sincerely,



A. Wes Siegnex, Jr.

AWS/ljg
Enclosure

0927.001.01

BFG52093

21739002