SEP 1 0 1968

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

September 12, 1968

Dr. R. Emmet Kelly
Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

Re: Food Additive Petition No. 8B2306

Dear Dr. Kelly:

We have completed our evaluation of the above-referenced petition and we are unable to conclude that the available data establish safety of the petitioned additive under the proposed conditions of use.

The following deficiencies were noted during our evaluation of the petition:

1. The petition lacks data on the chlorinated biphenyl impurity content of the material fed in the feeding studies reported in the petition.

2. The petition suggests GC method for the biphenyl content of the refined terphenyl and submits a GC curve (Appendix - Exhibit 1). This chromatograph raises several questions as follows:
   (a) What are the analytical conditions for the GC test.
   (b) Peak analysis indicates more than 1% of biphenyl.
   (c) High content of higher polyphenyls not indicated in original terphenyl composition or in Aroclor 5460.

3. It is our opinion that your proposed regulatory identification is inadequate to assure safety of the additive under the proposed conditions of use. We believe that the regulatory identification of the additive should include specifications for softening point, chlorine content, refractive index, and a specification that will serve to limit maximum chlorinated biphenyl impurities to a level no higher than that of the material fed in the feeding studies reported in the petition.

4. Please provide us with a copy of the standard analytical method that you use for determining the chlorine content of the additive.

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Since we are unable to recommend favorable action on the petition, we suggest you withdraw it without prejudice to a future filing if the above-listed deficiencies cannot be promptly resolved. Please let us know your intent in this matter within 30 days of the date of this letter.

Sincerely yours,

William F. Randolph

William F. Randolph
Petitions Control Branch
Bureau of Science

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