

# Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)

1825 CONNECTICUT AVENUE, N. W.  
WASHINGTON, D. C. 20009

September 7, 1967

TO: Members of the Food, Drug, and Cosmetic Chemicals Committee

SUBJECT: Report of Carcinogenicity Task Group

Gentlemen:

I am enclosing a copy of the report prepared by  
Drs. Treon, Shaffer, and Zapp for your consideration prior  
to the September 12 meeting.

Sincerely yours,



Morgan M. Hoover

MMH:sjg

Enclosure

August 28, 1967

Proposed Position Paper  
for MCA - FDCC Subcommittee  
on Carcinogenicity

We believe there is ample guidance in the published literature (1,2,3,4,5) to techniques for the conduct of tests for carcinogenicity. The important questions are the extent to which these tests should be used in the routine evaluation of the safety of chemical food additives, etc., under what circumstances such tests should be carried out; and what strains and species should be used as test animals.

Since the interest of the MCA is primarily in chemicals, as components of food and cosmetics, our comments will be confined to these classes.

Food chemicals reach the public by the ingestion route, and the Food Additive Amendment of 1958 takes cognizance, appropriately, of only those substances which are found to induce cancer when ingested by man or animals. We believe that this is a sound principle.

Any recommended test for carcinogenicity on or in animals should ~~therefore~~ be one in which the test substance is applied or administered by the route in which the public is to be exposed. For substances to be ingested, tests by parenteral injection (4,5) or topical application are of doubtful relevance and should not be required. For substances to be applied to the skin, topical application is the relevant route of administration, etc.

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Carcinogenicity is only one aspect of testing for chronic toxicity (1,5). We believe that it should be conscientiously looked for in the course of all tests performed to evaluate the chronic toxicity of a substance. If a chemical food or cosmetic additive produces no hint or suggestion of carcinogenicity in the course of all the tests currently required for the evaluation of the safety of such chemical additives, additional specific tests by other techniques or different routes of administration appear to us to be an unnecessary burden unlikely to produce results of practical significance.

The position, which we have enunciated here, is essentially that which has been taken by the FDA, since the Food, Drug and Cosmetic Act of 1938 was enacted and which we believe has been successful in protecting the public against the introduction of significant carcinogenic hazards into foods and cosmetics.

MANUFACTURING CHEMISTS' ASSOCIATION, INC.  
FDCC COMMITTEE,  
SUBCOMMITTEE ON CARCINOGENICITY STUDIES

*C. Boyd Shaffer*  
C. Boyd Shaffer, Ph.D.

*John A. Zapp*  
John A. Zapp, Ph.D.

*Joseph F. Treon*  
Joseph F. Treon, Ph.D.

*What Shaffer  
& Zapp Shaffer  
Tremor in muscle not  
definitely in dog or man  
a rule & cause of tremor*

August 28, 1967

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1. "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics", Association of Food and Drug Officials of U.S., 1959.
2. "Problems in the Evaluation of Carcinogenic Hazard from Use of Food Additives", Food Protection Committee of the Food and Nutrition Board, National Academy of Sciences - National Research Council, Publication No. 749, December, 1959.
3. "Evaluation of the Carcinogenic Hazards of Food Additives", Fifth report of the Joint Food and Agricultural Organization World Health Expert Committee on Food Additives, WHO Technical Report Series No. 220, 1961.
4. "Subcutaneous Sarcoma as an Index of Carcinogenic Potency", P. Grasso and L. Golberg, Food and Cosmetics Toxicology, 4 (No. 3); 297, June, 1966.
5. "Procedures for Investigating Intentional and Unintentional Food Additives", Report of a World Health Organization Scientific Group, WHO Technical Report Series No. 348, 1967.