

MAR 4 1968

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Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)

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

February 29, 1968

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

SUBJECT: MCA Statement on Carcinogenicity

Gentlemen:

Enclosed is a copy of the February 28, 1968 statement to the FDA Advisory Committee, which was prepared by Drs. Treon, Shaffer, and Zapp.

Sincerely yours,



Morgan M. Hoover

MMH:sjg

Enclosure

ASI 00002000

Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)

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

GEORGE H. DECKER
General, U.S.A. (Ret.)
PRESIDENT

February 28, 1968

Dr. Norton Nelson, Chairman
FDA Advisory Committee
c/o Institute of Environmental Medicine
New York University Medical Center
550 First Avenue
New York, New York 10016

Dear Dr. Nelson:

The Manufacturing Chemists Association would like to submit the following statement for the consideration of the Panel on Carcinogenicity of the FDA Advisory Committee. The Manufacturing Chemists Association is a nonprofit trade association of 183 United States and 14 Canadian company members representing more than 90% of the production capacity of basic industrial chemicals within these countries.

We believe there is ample guidance in the published literature (attached references 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, with respect to carcinogenicity, the Food Additive Amendment of 1958 by its terms bars those substances which are found to induce cancer when ingested by man or animals. We believe that this statutory emphasis on ingestion is a sound principle.

Tests for carcinogenicity on or in animals should be those in which the test substance is applied or administered by the route through 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.

ASI 00002001

Dr. Norton Nelson
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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 evidence 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 set forth above is essentially that which has been taken by the FDA since the Food, Drug and Cosmetic Act of 1938 was enacted. We believe it has been successful in protecting the public against the introduction of significant carcinogenic hazards into foods and cosmetics.

Sincerely,



G. H. Decker

Attachment

REFERENCES

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.