

MANUFACTURING CHEMISTS' ASSOCIATION, INC.

MINUTES OF MEETING

FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

MCA Conference Room Washington, D. C.

June 13, 1967

Members Present

W. E. McCormick, Chairman	B. F. Goodrich Company
V. H. Knoop, Vice Chairman	Mallinckrodt Chemical Works
T. R. Aalto	Tenneco Chemicals, Inc.
F. R. Barron, Jr.	American Cyanamid Company
R. N. Bell	Stauffer Chemical Company
C. P. Carpenter	Union Carbide Corporation
Frank DiPrima (for J. M. Stocker)	Merck & Co.
T. W. Hanavan	E. I. du Pont de Nemours & Company
James Hulse (for C. F. Hagan)	Chas. Pfizer & Co.
K. B. Kerr (for O. H. Peterson)	Salsbury Laboratories
W. A. Knapp	Allied Chemical Corporation
J. A. Korth	Corn Products Company
K. E. Mulford	Atlas Chemical Industries
W. H. Meyer	Procter & Gamble Company
A. M. Schnitzer (for R. P. Howard)	Phillips Petroleum Company
H. C. Spencer	The Dow Chemical Company
G. P. Vincent	Olin Mathieson Chemical Corporation
N. G. White	Shell Chemical Company
Samuel Zuckerman	H. Kohnstamm & Company
M. M. Hoover, Secretary	MCA Staff

Guests Present

L. S. Harrow	General Foods Corporation
Arthur Schramm	Stange Company
A. E. Settle	MCA Staff

Members Absent

C. F. Hagan	Chas. Pfizer & Co.
R. P. Howard	Phillips Petroleum Company
J. G. Kuniholm	Hercules Incorporated
A. R. Marusi (Board Liaison)	The Borden Company

Members Absent (cont'd)

L. A. Miller	Monsanto Company
O. H. Peterson	Salsbury Laboratories
H. L. Schulman	Washine Chemical Corporation
D. A. Seligman	Hoffman-LaRoche Inc.
J. M. Stocker	Merck & Co.

1. Minutes of the Last Meeting

The minutes of the January 25, 1967 meeting were approved as distributed.

2. Membership

The committee welcomed W. A. Knapp of Allied Chemical Corporation and J. A. Korth of Corn Products Company as new members of the committee. Dr. Knapp replaces B. T. McMillan, and Mr. Korth replaces J. T. Seawell.

The secretary announced the resignation of R. G. Troup of J. T. Baker Chemical Company.

3. Internal Liaison

MCA Public Relations Department - In response to the request of the committee, Mr. Settle reviewed the activities of the MCA Public Relations Department in the area of food additives. The committee expressed its thanks to Mr. Settle for an interesting presentation.

MCA Environmental Health Advisory Committee - The chairman announced his recent appointment of N. G. White as representative of the FDCC Committee to EHAC.

4. External Liaison

FDA Advisory Committee - The chairman announced his recent appointment of T. W. Hanavan (chairman), H. C. Spencer, and T. R. Aalto as members of an ad hoc subcommittee to make specific recommendations to the FDCC Committee at its ~~June~~^{Sept 13} meeting relative to the work of the FDA Advisory Committee, specifically the Panels on Reproduction Studies, Carcinogenicity, and Potentiation.

It was voted unanimously that three groups be established under the general direction of the ad hoc subcommittee, each to be staffed by toxicologists, and each to develop an MCA position concerning one of the panel subjects which would be presented orally and in writing to the FDA Advisory Committee and to the respective panel. There was general agreement that the statements should be coordinated with those of the NACA.

Dr. Carpenter agreed to head up the Reproduction Studies Group, and Mr. Hanavan agreed to recruit two others outside of the FDCC Committee to head up the Carcinogenicity and the Potentiation groups.

Codex Alimentarius Commission - Mr. Mulford reported that his task group (including Messrs. Hanavan and Kuniholm) has recommended that Dr. Spencer be nominated as MCA's choice for an industry advisor to attend the next session of the Codex Alimentarius Commission in Rome next January. The task group took into account the advisability of rotating this assignment, but felt that Dr. Spencer should again be nominated because of the need for continuity in the face of the changes in U.S. Government representation, and because of his excellent work in the past.

The committee unanimously accepted the recommendation of the task group, and the secretary was requested to make this action known to the chief U.S. delegate, expressing the hope that it will be received favorably. Dr. Spencer said that the committee should give thought to rotation in future nominations of industry advisors.

The secretary agreed to advise MCA member companies of the need for establishing a continuing liaison with the government people serving as U.S. delegates to the CAC. He also agreed to inform them of Dr. Spencer's nomination to serve as an industry advisor, and to urge that any comments and suggestions they may have regarding the work of the CAC be sent in prior to the January session. Members of the FDCC Committee were urged to send in their thoughts as well.

Food Chemicals Codex - Dr. Spencer reported that the Food Protection Committee of the NAS-NRC is implementing the matters of supplementation and reissue of the Food Chemicals Codex.

5. Carcinogenicity Task Group

No action was taken at the June 13, 1967 meeting to implement the May 15, 1967 recommendations of the task group.

Various suggestions were made as to the course to follow which included sponsoring a symposium, collecting papers and other information, and meeting with government experts at the Tri-City center. Thoughts were expressed as to the need for stimulating positive and constructive statements to offset the negative, the need for more research to establish the facts before spending further time on this subject, the need to find out what experience has been gained so far, and the need for further thinking as to what action to take.

6. Plant Inspections Task Group

The committee voted unanimously to accept the draft questionnaire of the task group with two minor revisions, subject to approval of the MCA Staff.

7. Other Items

Indirect Food Additives - The secretary was requested to ascertain from Dr. Frawley what data he now has so that the FDCC Committee can decide about its recommendation regarding his proposal.

Micro-Organisms - Mr. Lee Harrow of General Foods explained his company's philosophy and practice re controlling microbiological contamination, which was received with considerable interest by the committee.

Economic Poison Disclaimers - Discussion of this item was tabled until the next meeting of the committee.

Cosmetics Legislation - The secretary was requested to try again to obtain from TGA its thoughts.

Unsolicited Drug Samples Legislation - Messrs. Mulford and McCormick were requested to draft an appropriate letter on this subj ct.

Animal Care Legislation - The secretary was requested to continue to keep the committee advised of developments in this area. H.R. 8458 was mentioned specifically.

8. Next Meeting

It was decided to hold the next meeting of the committee on September 12, 1967 in the MCA Conference Room in Washington.

M. M. Hoover

M. M. Hoover, Secretary
FDCC Committee

MMH:sjg
June 14, 1967

ALLIED CHEMICAL CORPORATION
LEGAL DEPARTMENT

June 9, 1967

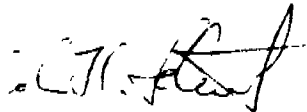
MR. KNAPP:

Re: Manufacturing Chemists Assoc. Inc.
Food, Drug & Cosmetic Chemicals Committee

We think that Allied Chemical should help the MCA as much as possible on the formulation of FDA plant inspection procedures.

As you are aware, our attitude has been to cooperate with the FDA inspectors unless they want information to which they are apparently not entitled.

We have insisted that requests for such information be made in writing. It is then evaluated by the Legal Department and others. Generally, the inspectors stay within the scope of legitimate inquiry.



John H. Lehnert

June 9, 1967

Mr. Morgan M. Hoover
Manufacturing Chemists Association, Inc.
1825 Connecticut Avenue, N.W.
Washington, D. C. 20007

Dear Mr. Hoover:

I regret delay in replying to your letters of February 28 and March 21, 1967 concerning supporting data for thesis presented by Dr. Frawley in his A.C.S. paper of last September. We have one compound (a pesticide), phenyldimethyl urea, $C_6H_5NHCON(CH_3)_2$, for which chronic feeding study was not published.

Phenyldimethyl urea has oral LD_{50} to rats intubated as 20% w/v suspension in 1% aqueous Methocel⁵⁰) of 3.9 ± 0.2 g/kg. A three-months feeding study at 0, 40, 200, 1000, 2500 and 5000 ppm in the diet produced no histopathology but did produce significantly increased liver weights in female rats at 2500 and 5000 ppm in the diet. In the two-year chronic feeding study, rats were fed at 0, 10, 50, 250, 1250 and 2500 ppm in the diet. No significant effect was observed as judged by growth rate, mortality, blood studies or histopathology.

With respect to migration studies on actual food samples, we have worked only with olive oil in contact with fluorine containing polymer films. Here, migration was very low not approaching that of rosin size. This work can be abstracted if desired.

Very truly yours,

Original Signed
E. A. Knapp

W. A. Knapp
Consultant-Toxicology

WAK:dmk