Manufacturing Chemists Association

MINUTES OF MEETING

FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

MCA Conference Room Washington, D. C.

April 2, 1969

Members Present

W. E. McCormick, Chairman	B. F. Goodrich Company
T. R. Aalto	Tenneco Chemicals, Inc.
R. N. Bell	Stauffer Chemical Company
C. F. Hagan	Chas. Pfizer & Co.
T. W. Hanavan	E. I. du Pont de Nemours & Company
W. A. Knapp	Allied Chemical Corporation
W. H. Meyer	Procter & Gamble Company
R. M. Miller	Hercules Incorporated
K. E. Mulford	Atlas Chemical Industries
P. E. Neiman	Enjay Chemical Company
O. H. Peterson	Salsbury Laboratories
R. F. Philpitt	Olin Mathieson Chemical Corporatio
Robert Ruark (for J. A. Korth)	Corn Products Company
H. C. Spencer	Dow Chemical Company
M. B. Ver Nooy (for C. P. Carpenter)	Union Carbide Corporation
M. M. Hoover, Secretary	MCA Staff

Members Absent

F. R. Barron, Jr.	American Cyanamid Company
C. P. Carpenter	Union Carbide Corporation
J. D. Early	Monsanto Company
P. J. Franks	Hoffmann-La Roche Inc.
V. H. Knoop, Vice Chairman	Mallinckrodt Chemical Works
J. A. Korth	Corn Products Company
A. M. Schnitzer	Phillips Petroleum Company
H. L. Schulman	Washine Division
N. G. White	Shell Chemical Company
Samuel Zuckerman	H. Kohnstamm & Co.

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1. MEETINGS

a. Minutes of Last Meeting - The minutes of the October 10, 1969 meeting were approved as distributed.

b. Next Meeting - The committee decided to hold the next meeting September 9, 1969 in either Washington or New York.

2. PERSONNEL

The committee voted unanimously to recommend to the MCA Board of Directors that P. E. Neiman of Enjay Chemical Company be appointed a member of the committee. The secretary announced that Frank DiPrima has left Merck and therefore would no longer be a member of the committee, and that Mallinckrodt has indicated it will take action to reduce its membership on the committee to one since Washine has become a division of Mallinckrodt.

3. LIAISON

a. MCA Board of Directors - Mr. Hagan conveyed Mr. Powers' regrets for not being able to attend the meeting.

b. MCA Environmental Health Advisory Committee - No report was received on EHAC activities from the FDCCC representative who was absent. However, the secretary read to the committee Minute 5.3 from the minutes of the March 6, 1969 EHAC meeting which referred to three major subdivisions of a suggested MCA environmental health program five years hence, one of which is "Consumer and public protection in reference to chemical products, e.g., labeling, food additives, etc." The committee voted unanimously to advise EHAC that FDCCC feels it to be important for EHAC to consider food additives in its planning and to keep FDCCC advised concerning this. In back of this vote was considerable feeling that something should be done to counteract erroneous public impressions concerning the health aspects of food additives, now that it appears this and other environmental health subjects will be receiving major attention in the political arena, and before the problem assumes greater proportions.

4. COMMITTEE PROJECTS

a. International Food Standards - Dr. Spencer and Mr. Ruark reported on the Sixth Session of the FAO/WHO Codex Alimentarius Commission which they attended and which was held March 4-14, 1969 in Geneva. At this session, a number of commodity standards were recommended to go to governments for acceptance. Among these were a group for fats and oils. The recommended fats and oils standards

provide for the use of some food additives which have not yet been endorsed by the Codex Committee on Food Additives, and which will be deleted from the final standards if this endorsement is not obtained at the next CCFA meeting in October, 1969. To expedite this endorsement, the Institute of Shortening and Edible Oils has undertaken to obtain the necessary toxicological data for establishment of acceptable daily intakes (ADI's) by the FAO/WHO Joint Expert Committee on Food Additives prior to CCFA action.

To expedite the endorsement of food additives to be included in commodity standards not yet presented to the Codex Alimentarius Commission for adoption as a recommended standard, the FDCC Committee voted unanimously to request the secretary to notify MCA member companies of those food additives for which ADI's have not been determined so that data on them may be forwarded to the Expert Committee. The importance of having ADI's established for food additives was emphasized by Mr. Ruark, Dr. Spencer, and others.

The FDCC Committee also recommended that the staff establish a continuing communication with the U.S. delegate to CCFA. Mr. Ruark and Dr. Spencer will work with the secretary to help establish a meaningful and mutually beneficial relationship.

Dr. Spencer expressed his appreciation to MCA for providing him the opportunity to serve as an industry advisor to the U.S. delegation.

The attention of the committee was called to the Symposium on International Food Standards to be held the morning of May 13 in Chicago in conjunction with the annual meeting of the Institute of Food Technologists. This symposium will be chaired by F. M. Depew with the following participating in the discussion: D. G. Chapman, G. R. Grange, M. F. Markel, M. R. Stephens, J. B. Stine, and Viggo Enggaard.

b. Proposed Good Manufacturing Practice Regulations - The secretary reported that the MCA statement concerning the revised proposed regulations was submitted to HEW February 17, 1969, and that copies of this statement were sent to the committee. He also reported on information received by phone from the FDA Bureau of Regulatory Compliance on April 1, 1969 concerning the status of these regulations. This information indicated that FDA is not prepared to provide for a blanket exemption for chemicals used for components of food as recommended by MCA, that a final regulation may be issued in the near future with 30 days allowed for compliance, and that FDA is prepared to amend the regulations at any time an industry reaches the conclusion there are sound reasons for exemption. It was the consensus of the committee that a meeting with FDA was in order at this time, and the secretary was requested to investigate this.

c. Proposed Food Additive Procedural Regulations - Dr. Knapp referred to the report "Quantitative Guidelines for Toxicologically Insignificant Levels of Chemical Additives in Food" prepared recently for the NAS/NRC Food Protection Committee. It was brought out that FDA intends to issue a new proposal following its review of the FPC report.

d. Protocols for Safety Evaluation - With respect to the FDA Advisory Committee activity, the secretary reported that the report of the Panel on Reproduction Studies has just been received by FDA, and that the report of the Panel on Cancer Testing is being drafted. He also reported that FDA has advised that a copy of each report could be made available to MCA following FDA review. The MCA statement to each panel has been distributed to the committee.

5. OTHER ITEMS

a. MCA Food Additives Manual - The secretary reported that there has been little demand in recent years for this manual, which deals with legislation, and requested the committee's advice concerning the need for updating. The committee, while recognizing that the manual did serve a useful purpose in the past, voted unanimously to recommend no reprinting or updating.

b. Microbiological Enforcement Activity - The chairman called the committee's attention to the item on this subject involving certain topical drugs and cosmetics which appeared in the TGA Executive Newsletter of February 18, 1969.

c. Joseph F. Treon - Mr. Mulford informed the committee that Dr. Joseph F. Treon of Atlas Chemical Industries passed away recently, and the chairman requested the secretary to send an appropriate MCA letter to his widow. In the course of assisting the committee with special projects from time to time, Dr. Treon had become well-known and well-respected by committee members.

M. M. Hoover, Secretary

MMH:sjg
April 18, 1969

Distribution "A"

FDCC Meeting

MCA Conference Room, Washington D.C 4/2/69

The notes below are in order of agenda, not in sequence discussed at the meeting.

(1) Mr Paul E. Neuman of Geigy introduced and later elected to membership on committee (item 3). Minutes of last meeting approved

(3) Mallinckrodt having acquired Washine Chem. Corp. relinquishes membership of H.L. Stuhlman on committee.

(4) (a) Powers sends regrets via Charles Hagan — on way to Europe (b) Dr White not present (c) Dr Spencer's report forgotten probably because McCain not present when Pearl reported (d) [illegible] reported slow progress (e) Meyer report forgotten. With respect to Codex reports the Bob Miller urged more formal notification of items being considered by Codex Committee. U.S. Food Additives not considered by these committees will have very difficult time getting future approvals. Our Secretary was requested to prepare list of additives used in U.S. and not being considered by present committees.

With respect to Codex discussion above Walt Meyer (P&G) reported that 12-13 additives for fats + oils which have advanced to Step 9 have not been considered by the Food Additives committee and are therefore not ready for Step 9 because no ADI'S have been set.

Mr Pusack (Corn Products) reported that meeting of the Expert Comm would be held on May 27 or June 1st at Geneva depending upon availability of an Italian expert. Mr R's Comm (Food Additives) will meet at Arnheim, Germany on Oct 16-24. It has been noted that FA Comm must supply own methods of analyses i.e. they will not be supplied by Codex Anal. Com.

5 (a) Dr Prema has left for Mexico and not present. The writer expressed disappointment (Barnard of FDA) from at probable FDA action and insistence GMP regs were not written for chemical manufacturers. Dick Phelps suggested matter not being handled at high enough level in FDA despite [illegible] by Decker on MCA and

(b) Knapp reported on FPC report to FDA (Food Chem. News of 7/3/69 pgs 29-35. Bob Miller stated that FDA statement was expected shortly.

(c) Hoover reported status of MCA statements on Safety Eval - it is not likely that MCA rec. on repro. studies will be adopted; FDA wants more than single generation;

ASI 00002288

6. Mr Howe requested discussion on reprints of MCA Food Additive Memos Pts 1 & 3 in one pamphlet, Pt 4 in another. Motion passed that these have served their purpose but no longer needed. In discussion of this subject it was brought out (Milford) that while new Public Relations effort on Food Additives is needed. Heat is presently on drug but food additives a prime future target for publicity concern members of Congress, Nader's Raiders etc. In this connection the Suggrenes report at SOT was said to have created crisis in FDA (by) Bionetics study was very expensive and paid for by National Cancer Institute (NCI). A letter has gone to MCA executive contacts listing products tested; a copy of preliminary report (Bionetics) is available at MCA office (Mr Geschickter) for review but may not be copied.

In further general discussion relevant to above it was the opinion of most present that (1) Environmental health (2) Occupational Health and (3) Consumer Protection would be major problems for the 70's. Motion was made and passed that EHAC be advised that FDC considers Food Additives as a very important area of their activities. It should have a high priority in the MCA scheme of activity.

7. With respect to Upjohn letter requesting guarantee of membrane sterility it was the opinion of attorneys present (Hansen, Milford) that it was impossible to guarantee absence of bacteria. Nevertheless the standard guarantee or a U.S.P. claim etc. is merely given does guarantee absence of bacteria within intent of FDC Act. The difficulty is that standards and test methods have not been established and are not likely to be in the near future. It is

(over)

understood that the NAS report to FDA on Salmonella has not been published and will not be, it is an interim report. It is also understood that this report recognizes a Salmonella problem but makes no attempt to set standards or test methods; free is virtually impossible.

With respect to guarantees it would be difficult to prove that bacterial contamination occurred before or after opening of the container. If product loss occurred via tampered contamination and it could be traced to your product liability for damages would be possible

8. Next Meeting - Sept 9, 1969