Manufacturing Chemists' Association, Inc.

MINUTES OF MEETING

FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

MCA Conference Room Washington, D. C.

September 12, 1967

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Members Present

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

Guests Present

Daniel Badia	Chas. Pfizer & Co.
R. F. Philpitt	Olin Mathieson Chemical Corp.
Joseph Treon	Atlas Chemical Industries

Members Absent

F. R. Barron, Jr.	American Cyanamid Company
C. F. Hagan	Chas. Pfizer & Co.
R. P. Howard	Phillips Petroleum Company
J. G. Kuniholm	Hercules Incorporated
A. R. Marusi, Board Liaison	The Borden Chemical Company
W. H. Meyer	Procter & Gamble Company
L. A. Miller	Monsanto Company

O. H. Peterson	Salsbury Laboratories
H. L. Schulman	Washine Chemical Corp.
D. A. Seligman	Hoffman-LaRoche
J. M. Stocker	Merck & Co.
Samuel Zuckerman	H. Kohnstamm & Co.

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1. Minutes of the Last Meeting

The minutes of the June 13, 1967 meeting were approved as distributed.

2. Membership

The secretary reported that no new members were added to the committee since the last meeting.

3. Liaison With FDA Advisory Committee

Mr. Hanavan reviewed what has been done by the FDCC Committee up to this time for the purpose of presenting its views regarding protocols to the Panels on Reproduction Studies, Carcinogenicity, and Potentiation of the FDA Advisory Committee. Corresponding task groups have been established within the FDCC Committee to prepare recommendations.

Dr. Carpenter reported on the response to the questionnaire for reproduction data, which indicates that the three-generation test is no more sensitive than the two-year feeding test. He cautioned that it could be more sensitive, however, depending on how it was conducted, and that the raw data may have to be presented for examination by the Panel on Reproduction Studies. Dr. Frawley reported that the single study performed by a university, which indicated that the three-generation test is more sensitive, is being repeated and may take a year.

It was unanimously voted that MCA prepare a statement for the consideration of the Panel on Reproduction Studies which points out that our data for approximately 17 compounds supports the recommendation made previously by NACA based on approximately 48 compounds.

Dr. Treon summarized the draft position paper prepared by his task group for consideration of the Panel on Carcinogenicity. This paper states in part that carcinogenicity is only one aspect of testing for chronic toxicity, that it should be conscientiously looked for in the course of all tests performed to evaluate the chronic toxicity of a substance, and that 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 tests by other techniques or different routes of administration (other than ingestion) appear to be an unnecessary burden unlikely to produce results of practical significance.

It was unanimously voted that the position paper (with an editorial revision) be presented to the Panel on Carcinogenicity, and that a modification be made if subsequent developments indicate a need for this. The editorial revision is to correct the impression in the third paragraph that the FDCC Committee feels that the Delaney amendment to the Food, Drug, and Cosmetic Act is sound. The chairman requested Dr. Treon and Mr. Mulford to make this revision.

Dr. Frawley reported that there is as yet no protocol covering the broad aspects of potentiation for the Panel on Potentiation to evaluate, and that a recommendation in favor of deleting a requirement (F.R. 120.35) regarding the testing of organic phosphate pesticides has apparently been accepted. He agreed to keep the FDCC Committee informed regarding protocols involving potentiation.

The secretary reported that the scheduled early October meetings of Panels on Reproduction Studies and Carcinogenicity have been postponed, one reason being that the list of questions to be sent out by the Panel on Carcinogenicity has not yet been prepared. He was informed by Dr. Nelson that we will be advised as soon as the meetings are re-scheduled.

4. Liaison With Codex Alimentarius Commission

Dr. Spencer reported that the second meeting of the Codex Committee on Food Additives is being held this week in The Hague, that a meeting of the Codex Committee on Pesticide Residues is to be held next week, and that the next session of the Codex Alimentarius Commission will be held next January in Rome.

With regard to the latter, Dr. Spencer (who has been nominated by MCA as an industry advisor to the Chief U.S. Delegate) indicated he will work out a plan so that his efforts in Rome will be coordinat d with those of Messrs. Ruark, Frawley, and Meyer who are industry advisors to the U.S. Delegates to the Codex Committees on Food Additives, Pesticide Residues, and Food Labeling respectively.

Dr. Frawley reported that there have been innumerable difficulties in obtaining data, and that no one is happy about the decisions being made by the Expert Committees. He will recommend a change in the relationship of the Expert Committees to the Codex Committees, and a change in the method of establishing acceptable daily intakes to take into account variations in the amounts of individual foods consumed in various countries.

Dr. Frawley said also that the FDA will probably yield to the Codex standards as they emerge, and that customers will demand conformance with them even if FDA doesn't. It was brought out that a food manufacturer will not wish to produce two types of each food, one for domestic and another for foreign consumption.

The secretary commented that the chemical industry's methods for dealing with such an important subject as international food standards appear to be much too haphazard, and that something should be done to correct this. After discussion of this point, the committee voted unanimously to request the chairman to appoint a task group to study the matter and to give a report at the next meeting. Mr. Mulford expressed the opinion that the group should include in its work consideration of what this country should do when Codex standards are submitted for adoption.

5. Proposed Revision to FDA Food Additives Procedural Regulations

After a discussion of the proposed revision, the committee voted unanimously to request an extension of 60 days in the time permitted to file written comments. This request is to include the reason for requesting the extension, which is that the complexity and far-reaching implications call for it.

It was also voted unanimously to request the chairman to appoint a task group to review the sets of comments already prepared (as well as those to come) and make a recommendation as to what MCA should do. The chairman then appointed Dr. Knapp (chairman), Mr. Hulse, and Dr. Vincent to the task group. He also requested the secretary to send a letter to the committee requesting comments to be sent to the task group within two weeks. The recommendation of the task group is to be sent to the committee for letter ballot.

6. Other Items

MCA Environmental Health Advisory Committee - Dr. White reported on the recent EHAC meeting at which quidelines for further activity were developed, and announced that a meeting of EHAC will be held September 14 to implement them.

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Indirect Food Additives Proposal - The secretary reported that Dr. Knapp's data has been turned over to Dr. Frawley, and that Dr. Frawley has expressed the belief that we will be in a better position to request action by FDA on his proposal once the information is in the scientific literature which will be soon.

Plant Inspections - It was voted unanimously to table action on the survey reported in previous minutes unless and until a greater demand for it arises. Based on comments made at recent meetings, it had been decided that a survey was needed.

Microbiological Contamination in Food Chemical Plants - It was concluded that the answers given at the last meeting with respect to food plants suffice.

Economic Poison Disclaimers - It was concluded that this subject is not too much of a problem at the moment.

Cosmetics Legislation - Because of concern over possible undue restrictions on the number of permissible cosmetic chemicals, the secretary was requested to contact TGA and possibly PMA and others to find out what is being done in the area of cosmetics legislation.

Unsolicited Drug Samples Legislation - Mr. Mulford reported that a draft recommendation has been prepared which can be brought into final shape without much effort should H.R. 3954 come up again.

Recordkeeping Legislation - Mr. Knoop reported that H.R. 11804 is of interest only to those products covered by the Drug Abuse Control Act. Purpose of the bill is to remove from the law the provision which stipulates that ordinary business records will suffice. Since there is nothing to suggest any activity, Mr. Knoop recommended no action.

Food Supplements Definition Legislation - Mr. Knoop reported that H.R. 11837 is designed to negate FDA regulations on food supplements, that the administration will probably oppose the bill if it acts, but that the bill is of little practical importance.

Animal Care Legislation - The secretary reported that no consideration of H.R. 8458 by the House Interstate and Foreign Commerce Committee has been scheduled and probably won't be in this session of Congress.

7. Next Meeting

It was decided that the next meeting of the FDCC Committee will be held February 20, 1968 in the MCA Conference Room in Washington.

M. M. Hoover, Secretary

MMH:sjg
September 15, 1967