

Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)

1825 Connecticut Avenue, N. W.
WASHINGTON 9, D. C.

PLAINTIFF'S
EXHIBIT
CMA-169

MINUTES OF MEETING
LABELS AND PRECAUTIONARY INFORMATION COMMITTEE
THE PITTSBURGH HILTON HOTEL
WEDNESDAY, SEPTEMBER 27
TRADERS ROOM C
THURSDAY, SEPTEMBER 28
CHARTIERS SUITE B
PITTSBURGH, PENNSYLVANIA

The meeting came to order at 9 A.M. on Wednesday, September 27, 1961.

PRESENT

Edward J. Hogan, Chairman	Allied Chemical Corporation
R. G. Troup, Vice Chairman	J. T. Baker Chemical Company
Robert H. Dewey	Commercial Solvents Corporation
Fred Ebersole	General Aniline & Film Corporation
Chester L. French	Mallinckrodt Chemical Works
J. T. Fuess	Eastman Organic Chemicals Department, Distillation Products Industries, Division of Eastman Kodak Company
Joseph T. Gormally	Pennsalt Chemicals Corporation
James W. Hammond	Humble Oil & Refining Company
Edward J. Masek	Diamond Alkali Company
Harry H. McIntyre	The Dow Chemical Company
George E. Merryman, Jr.	Union Carbide Canada Limited
J. A. Mooney	FMC Corporation
Thomas W. Nale, M.D. (September 27 Only)	Union Carbide Corporation
John F. Osteritter, M.D.	Celanese Corporation of America
Richard F. Philpitt	Olin Mathieson Chemical Corporation
G. Robert Sido	Monsanto Chemical Company
F. D. Sparre	E. I. du Pont de Nemours & Co., Inc.
N. E. Wendt	American Potash & Chemical Corporation
J. D. Kittelton, Secretary	Manufacturing Chemists' Association, Inc.

GUEST

Donald P. Smoot	Stauffer Chemical Company
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ABSENT

nford J. Hill	E. I. du Pont de Nemours & Co., Inc.
B. Shaffer	American Cyanamid Company
Norman G. White	Shell Chemical Company

It was moved, seconded and voted

THAT, The minutes of the LAPI Committee meetings of June 26-27 and August 22, 1961 stand approved.

1.2 SUBCOMMITTEE ACTIVITIES

(a) Pesticides

Mr. Sparre reported that all of the activity of the Pesticide Subcommittee was concerned with revision of the Manual reported under item 5.0.

(b) Dyestuffs

Dr. Ebersole distributed a copy of his report to the members in attendance, reporting continued progress in reviewing dyestuff labeling within the SOCMA group. Dr. Ebersole will keep the Committee advised of future developments.

(c) Reactive Metals Subcommittee

Mr. Wendt reported that the activity of his Reactive Metals Subcommittee was concerned with the revision of the Manual reported under 5.0.

(d) Revised List of Subcommittee

The Vice Chairman, Mr. Troup, discussed with Committee members a revised list of Subcommittee appointments which had been discussed previously by him and by Mr. Hogan and Mr. Kittelton. Committee members made several suggestions which were accepted by Mr. Troup and the revised list was approved to cover current activity. A copy of the list will be sent by the Secretary to Committee members.

1.3 ALLIED SUBCOMMITTEE ACTIVITIES

1.3.1 CSMA

Messrs. Sparre, McIntyre and Hammond agreed that the major portion of the CSMA activities in the labeling field had been devoted to the Federal Hazardous Substances Labeling Act and to the regulations, which was reported in detail under item 2.1.

1.3.2 API

Mr. Hammond filed a report with the Secretary which

reads as follows:

"The New York Petroleum Council is working closely with CSMA on a petition opposing the New York City Fire Department's regulation on flammable propellants in aerosols."

"The API made a petition to FDA on July 13 opposing several sections of the proposed regulations. This presentation was presented by representatives of the API and also by several individual companies. The FDA accepted some of these recommendations."

"The API bulletin on precautionary labels is not out of press. This second edition should be released in 1962."

1.3.3 NPV&L

Mr. Sparre reported that NPV&L hoped to be able to endorse the CSMA position on the final regulations. NPV&L expects that it will be able to obtain a special regulation on pigmented paints. These would be paints on high viscosity.

1.3.4 ACGIH

Mr. James Hammond's report on ACGIH activity is consolidated with his report on AIHA.

1.3.6 NFPA

Mr. McIntyre said that there was no Committee activity to report at this time. The NFPA Guide has been published and NFPA is awaiting "use" experience to make revisions.

1.3.9 AIHA

- (a) Paper by Mr. Hammond at 8th Annual Pacific Northwest Industrial Health Conference

Mr. Hammond reported briefly on his paper which he delivered at the recent Pacific Northwest Meeting.

Mr. Hammond gave the Secretary the following abstract of the paper:

"The need for proper precautionary labeling of chemicals and mixtures of materials has been recognized and practiced for almost 30 years in the United States. Recently enacted legislative regulations of precautionary labeling for household products and expanded state supervision of industrial substances have increased industry's responsibility in this field.

"Although the materials from the petroleum industry, with which we are associated, are only examples of the great number of products available on the market, they serve to represent the use of all guided principles in the selection of appropriate labels.

"One may obtain help for labeling of products, as well as the interpretation of the legend on labels, in handbooks of various trade organizations. Among the industrial organizations that have issued manuals and guides in this field are (1) Manufacturing Chemists' Association, (2) American Petroleum Institute, (3) Chemical Specialties Manufacturing Association and (4) National Paint, Varnish and Lacquer Association. The Federal Act is explained in the Federal Register and many states have their regulations available in suitable form for easy reference by interested persons.

"The purpose of labeling of hazardous materials is illustrated by the legend used on typical chemicals in industry and commerce."

Mr. Hammond said that in the Question and Answer Period he had an opportunity to mention the new edition of the LAPI Manual together with the availability of the MCA Safety Data Sheets.

(b) Questionnaires by AIHA and by Boeing Aircraft

Committee members briefly discussed questionnaires which are being distributed by the Pacific Northwest Section of AIHA and by Boeing Aircraft. The AIHA questionnaire is concerned with statutes or guides used in preparing warning labels for hazardous chemicals. The Boeing Aircraft questionnaire asks for information concerning the toxic properties of its suppliers' products.

(c) AIHA - Idaho Falls Meeting

Mr. Sparre reported that Mr. Hill had attended a meeting of the AIHA in Idaho Falls. Mr. Sparre said that there was considerable discussion at this meeting concerning industry precautionary labeling programs.

A suggestion was also made to Washington State officials that they consider the adoption of a regulation covering industrial chemicals similar to that now utilized by the state of New Jersey.

2.0 REGULATIONS

2.0.1 International

2.0.3 ABCM

The consensus of opinion among Committee members was that active liaison should be continued between MCA and ABCM. The Chairman said that at the next opportunity he would discuss this matter further with Mr. Crass.

2.1 FEDERAL LEGISLATION

(a) CSMA Meeting with FDA Officials Concerning Final Federal Hazardous Substances Labeling Regulations

Dr. Nale reported to the LAPI Committee a meeting which he attended with other CSMA representatives to discuss with FDA the lack of alternative methods in the regulations. Dr. Nale said that a number of objections were registered to the methods as set out in the final regulations.

In the afternoon a number of CSMA representatives talked to Messrs. Harvey and Clark concerning a series of important objections which industry still has to the final labeling regulations.

Mr. Sparre pointed out that Mr. Ackerly had not covered one important point in his memorandum and that was concerned with the manner in which FDA proposes to handle products under the Federal Caustic Poison Act. The final regulations state that "Poison" will be used on the label in place of the signal word. Mr. Sparre pointed out that this leads to a ridiculous situation in that a 5% solution of ammonia water would have to be labeled the same as concentrated sulfuric acid.

It was agreed by the Committee that it would recommend to MCA that it endorse CSMA recommendations in a communication to the Food and Drug Administration.

(b) LAPI Committee Review of Final Hazardous Substances Labeling Regulations

Before beginning a review of the final regulations, it was agreed by the Committee that MCA should file with the Food and Drug Administration all remaining objections which the LAPI Committee still has to the final regulations. This is for the purpose of the record so that the chemical industry will not later be placed in a position of having to accept portions of the final regulations with which they were not in accord.

Mr. Hogan asked if all of the companies represented on the LAPI Committee planned to send letters to the Food and Drug Administration concerning their objections to the final regulations. A number of LAPI Committee members indicated that their companies would not do this.

There was considerable discussion regarding the effect of the final regulations upon all MCA members.

After this discussion.

It was moved, seconded and voted

THAT, The Chairman appoint a Subcommittee to draft a letter explaining to members of the Association through their Executive Contacts and the Labeling Contacts the far-reaching effects the final Hazardous Substances Labeling Regulations issued on August 12th will have on them and,

It was further moved, seconded and voted

THAT, MCA send out this letter to the Executive Contacts and to the Labeling Contacts together with a copy of the MCA letter of comment which will be filed with the Food and Drug Administration covering MCA objections and recommendations on the final regulations, with the recommendation that each member company write the Food and Drug Administration in detail on their objections to various sections with which they are particularly concerned and also state their support of the MCA letter of comment.

This motion was passed unanimously and the Chairman appointed Messrs. Troup, Masek, Dr. Osteritter and Mr. Kittelton to this Subcommittee.

(1) Sections 191.1(c) and (d); 191.1(r)

The Committee was of the opinion that any reference to "purchase" or "purchaser" should be deleted from the final regulations since the Act was directed at the handler or user of the hazardous substance and not at the "purchaser."

(2) Section 191.1(f)

The Committee carefully considered this section and was of the opinion that the upper limit for a toxic substance should be set at 500 milligrams with FDA issuing a list of toxic substances falling within a range above 500 milligrams.

Dr. Nale also suggested that we repeat in our letter to FDA, arguments which had been made in the original MCA brief concerning animal tests to determine inhalation toxicity.

Dr. Nale agreed to submit acceptable alternative test methods to accompany the MCA letter of comment.

(3) Sections 191.10, 191.11, 191.12

As has been stated on a number of occasions, these sections are deficient in that they do not provide for any alternative tested methods. It was suggested that MCA, in commenting on these sections strongly recommend revisions to provide acceptance of "data from any other equally valid and reliable method."

(4) Section 191.1(o)

The Committee was of the opinion that Section 191.1(o) was still too broad and it was agreed that the recommendation used in the previous MCA brief should be repeated.

(5) Section 191.1(p)

The Committee felt that this definition was still deficient since the last sentence had been taken out of context from the House Report on the Federal Hazardous Substances Labeling Act and required revision as originally recommended in the MCA brief.

(6) Section 191.1(r)

The Committee considered this definition and agreed on the following wording:

"(r) Reasonably foreseeable handling or use. This includes the reasonably foreseeable accidental handling or use, not only by the intended user of the product, but by others in the household, especially children."

(7) Section 191.7

The Committee next considered the products which FDA listed in Section 191.17 requiring special labeling. The first product mentioned is carbon tetrachloride and mixtures containing it. The Committee agreed that this was too broad since no percentages were specified. Harry McIntyre in his letter of comment on the final regulations suggested that 5% would be a more realistic limit.

It was also agreed that objection should be raised to the listing of diethylene glycol and ethylene glycol.

(8) Section 191.14

Dr. Nale reminded the group that Mr. Duggan of his company had raised a number of serious objections to the requirements of this section. Mr. McIntyre also indicated objections and promised to check into the matter. The Secretary said that he would investigate the Bureau of Mines' method referred to in Mr. Duggan's communication to Dr. Nale.

(9) Section 191.61

It was pointed out that the exemption which MCA requested in its original brief for products containing distilled spirits was not granted by the Food and Drug Administration. Mr. Hogan stated that he had received a letter from the Secretary suggesting that this matter be handled by the MCA Industrial Alcohol Technical Committee. It was agreed that the Industrial Alcohol Technical Committee would send a letter to the Food and Drug Administration again requesting the proposed exemption and provide the LAPI Committee with copies of the correspondence.

(10) Section 191.101

It was the consensus of the Committee that FDA exceeded its legislative authority by requiring anything on the front

panel. It was agreed by the Committee that the following statement would be recommended to FDA as the front or main panel requirement:

"See Warning Caution Danger Statement on Side Back Panel."

It was also agreed that the Committee still did not see any reason why point type size requirements should be in the regulations, since the statute contemplated a number of ways to achieve conspicuousness.

(11) Section 191.109

This section as revised indicates that the word "Poison" on the labels of listed caustic poison substances will be required instead of any signal word. Dallas Sparre again pointed out the impracticability of this requirement since it would mean that weak ammonia water would have to be labeled the same as 100% sulfuric acid. Mr. Sparre also pointed out that other corrosives not included in the list would have to carry different labeling than that required by Section 191.109. Mr. Sparre will send to the Secretary some material to be included in the MCA letter to the Food and Drug Administration.

(12) Section 191.215

The Committee next considered Section 191.215 which is headed "Transitional Period for Relabeling." This section would authorize the use of stickers on containers of hazardous substances. The Committee was of the opinion that this method is unrealistic and impractical.

It would be very expensive to do this and in many cases it would impose severe hardships in prohibitive costs to smaller businesses without any insurance that the stickers would adhere to the container even if the dealers handled the relabeling properly.

The Committee then discussed the problem of stocks which would be in the hands of sellers on the effective date of the regulations and it was agreed that if possible it would be desirable to add a provision to the regulations that labels in reasonable compliance with Section 2(p)(1) of the Act would be recognized by the regulations.

(c) Extension Legislation

The Secretary distributed copies of H. R. 9347 to Committee members present. This bill was introduced by Representative Kilgore of Texas and would amend Section 16(b) of the Federal Hazardous Substances Labeling Act to authorize the HEW Secretary to grant extensions of 12 months beyond February 1, 1962.

Mr. Hogan said the Secretary had agreed to keep a file on any material relating to the extension and also all comments of industry organizations and MCA member companies on the revised regulations so that a record would be compiled as requested by Senator Magnuson.

It was also agreed that it would be desirable for MCA members to write their Senators and Congressman concerning the need for the extension. It might be well to do this by late November or early December.

2.2 STATE LEGISLATION

2.2.2 Illinois

Dr. French reported that there had not been any recent meetings of the Advisory Committee on the Illinois Hazardous Substances Labeling Act of which Dr. French is a member. The Legislature this year adopted H. 1636, a bill containing amendments to the Illinois Hazardous Substances Labeling Act, and the bill was signed into law by the Governor. This new law brings the Illinois Act into line with the new Federal Act.

Mr. McIntyre pointed out that there were some significant features in H. 1636. These are: (1) The Illinois Director of Health may declare certain substances to be hazardous substances; (2) Pesticides must be registered to be exempt from the Act; and (3) Any Federal action takes precedence.

2.2.7 New Jersey

The Secretary reported that New Jersey Assembly Bill 365 had passed the Assembly and had been sent to the Senate Business Affairs Committee on May 1st.

2.2.8 New York

The Secretary reported that A. 3623 in New York had died in the House.

2.2.9 Ohio

Mr. Masek said that no meetings of the Ohio Advisory Committee on the Ohio Hazardous Substances Labeling Law had been called.

2.2.21 Minnesota

The Secretary reported that Minnesota had approved a State Hazardous Household Act at a special session of the Legislature and that a copy of the Act had been sent to each Committee member.

2.2.23 Missouri

Dr. French reported that the Missouri Legislature adjourned without taking any action on S. 249.

2.3 CITY REGULATIONS

2.3.1 New York City

Mr. Hogan reported that CSMA had issued a bulletin on New York City's action in proposing the outlawing of flammable gases in aerosols. These regulations are now in effect but New York City has not yet taken any steps to enforce them.

2.3.1 Los Angeles

Mr. Hogan said that he had received the files on the Los Angeles Regulations from Mr. Mayhood and that he would soon turn them over to Dr. French with a report to permit the Subcommittee to develop a procedure and prepare formal comments for consideration by Fire Marshal Hill when presented by Mr. Mayhood. It is hoped to soon take some action concerning this matter.

3.0 LABELS -- SAFETY DATA SHEETS

3.69 Boron Hydrides

Mr. Wendt reported that as a result of a communication which Mr. Stephenson of General Safety Committee had received from the Bureau of Mines a change was made in the labels for Decaborane and Diborane. The statement concerning the use of a gas mask would read as follows:

DECABORANE

"Always wear self-contained breathing apparatus or full-face air-line respirator when using this chemical."

DIBORANE

"Have available emergency self-contained breathing apparatus or full-face air-line respirator when using this chemical."

Mr. Wendt said also that as a result of a review of the final Medical Section of the Safety Data Sheet on Boron Hydrides, the Decaborane label was changed to indicate that symptoms may be delayed for 48 hours instead of 72 hours.

3.80 Chloroform

Mr. Masek said that he had checked the draft of the Safety Data Sheet on Chloroform with his technical representatives and it was their opinion that Section 10.1.4 did not emphasize the danger of decomposition products, especially where there is contact with a hot surface.

Some of the precautionary labels being used by MCA members emphasized this danger and it was the consensus of the Committee that this matter should be thoroughly investigated by the Clearance Subcommittee as it relates to this and other materials.

3.81 Acrolein

Mr. Wendt said that he had not yet seen a copy of the final Medical Section and for that reason was not prepared to make a final recommendation concerning the proper precautionary label.

5.0 REVISION OF MANUAL L-1

- (a) Report on Meeting of Revision Subcommittee with General Hull

Dr. French reported that at the recent meeting of the Revision Subcommittee, Mr. Hogan had explained carefully to General Hull the reasons why the Committee did not feel a change in the title of Manual L-1 would be desirable. Mr. Hogan cited a number of statements in the Manual which made it very clear what subject matter was covered in the new Manual. These statements

reiterated the LAPI Committee's position that all requirements of applicable Federal, State and Local laws and regulations should be carefully reviewed and considered in addition to the suggestions incorporated in Manual L-1.

As a result of a thorough review of currently available facts on Anhydrous Ammonia and LAPI Committee policy by the MCA Staff and members of the Manual Revision Subcommittee, it was agreed to delete the Anhydrous Ammonia label text from the new edition of Manual L-1. The Manual Revision Subcommittee then recommended that a letter ballot be sent to the LAPI Committee covering this recommendation. The Secretary reported that the LAPI Committee had voted 18 to 2 to delete a label for Anhydrous Ammonia from the Revised Manual. Mr. Hogan also reported that General Hull had agreed that the MCA would initiate a review of the current Safety Data Sheet on Anhydrous Ammonia.

(b) Plans for Distribution of Revised Manual

The Secretary reported that a special announcement of the publication of the Revised Manual would be sent to those who had returned the card which was enclosed in the last edition of Manual L-1. In addition, the Secretary said that arrangements would be made to provide complimentary copies of the Manual to Federal, State and Local Officials directly concerned with precautionary labeling matters. The LAPI Committee has worked with many of these officials in developing precautionary labeling laws or regulations.

The Secretary stated that he would appreciate receiving from LAPI Committee members the names of government officials they believed should receive a complimentary copy of the Manual.

6.0 LABELING CONFERENCES

(a) Possible Conference with CSMA

The Chairman said that he would discuss this matter with CSMA Officials at the Inter-industry Precautionary Labeling Meeting.

(b) Possible Joint Industry-FDA Conference

A possible Joint Industry-FDA Conference on the Federal Hazardous Substances Labeling Act and regulations was briefly discussed by the Committee with no final determination being made. It was agreed that this idea might have merit and should be kept in mind as a possible future activity.

32.0 POISON CONTROL CENTERS

Mr. Hammond stated that according to a recent article in the Journal of the American Medical Association there are exactly 460 Poison Control Centers in the United States. The article which appeared in the September 9th issue of the Journal of the American Medical Association is attached as Appendix A.

MISCELLANEOUS

(a) Panel on Precautionary Labeling at Semi-Annual Meeting

Mr. Hogan reported that a panel on "What the New Federal Hazardous Substances Labeling Act and Regulations Means to Your Company," would take place at the MCA Semi-Annual Meeting in New York City on November 21st. The panel moderator will be Chairman of the LAPI Committee and panel participants will be Mr. James Hammond of Humble Oil, George Scriba of Union Carbide Corporation and Franklin D. Clark of Food and Drug Administration.

(b) Gordon Research Conference

The Chairman reported that Dr. Shaffer had called him and had asked for an MCA representative to present a paper at the 1962 Gordon Research Conference, a presentation of which will be concerned with "Toxicity and Safety Evaluation." The Chairman contacted Dr. Nale who agreed to present a paper.

(c) Letter from John Williamson

Dr. French read a very nice letter which he had received from John Williamson. Mr. Williamson again invited Committee members to visit him in the event that they are traveling in Virginia. All Committee members agreed that it was a very nice experience to once again see Mr. and Mrs. Williamson.

(d) National News Article on Flammable vs. Inflammable

Committee members briefly discussed the article which had been distributed by Dr. French concerning the use of the term flammable vs. the use of the term inflammable. It was the general consensus of the Committee that there was very little new in the article.

(e) 1962 Transportation and Packaging Symposium

Dr. French reported that he would be moderator of one of the sessions of the 1962 Transportation and Packaging Symposium. There will be one paper presented which will include some aspects of precautionary labeling. Dr. French said that he thought that anyone interested in packaging and transportation would like to know that the Symposium will be held in St. Louis on March 13-14, 1962.

(f) Next Meeting of Committee

It was agreed that the next Committee meeting will be held in Washington, D. C. on Tuesday and Wednesday, January 16-17, 1962.



James D. Kittelton, Secretary
Labels and Precautionary
Information Committee

JDK/hgs

Attachment

C O P Y

C O P Y

ATTACHMENT A

U.S. POISON-CONTROL CENTERS NOW TOTAL 460

The number of poison-control centers affiliated with the National Clearinghouse for Poison Control Centers rose to a new high of 460 as of July 1, Surgeon General Luther L. Terry of the Public Health Service announced.

"That the poison-control center fills an urgent and widespread need is evident from the rapid growth of the movement since the first one was established in Chicago in 1953," Dr. Terry said. "It is also interesting to note that the movement was started by practicing physicians, in this case pediatricians, rather than by public health agencies. It was centered and coordinated in the Public Health Service in 1957 on the recommendation of the physicians operating the individual facilities."

The National Clearinghouse for Poison Control Centers serves local centers by providing information on new products which it obtains through a voluntary arrangement with manufacturers. Over 200 major producers of drugs and household products inform the clearinghouse of the ingredients their products contain and the antidotes for them. The clearinghouse is directed by the PHS Division of Accident Prevent, headed by Assistant Surgeon General A. L. Chapman.

"Because many parents do not recognize the poisonous qualities of many common products, they sometimes delay too long before calling a physician," Dr. Chapman said.

"Many serious consequences of poisoning could be prevented if parents called physicians promptly without waiting for symptoms to appear," he added.

Aspirin tops the accident list for fatalities to small children. About 50% of substances swallowed are medications. Some other common harmful products that are swallowed are kerosene, bleaches, detergents, soaps, waxes, polishes, lighter fluids, cosmetics, insecticides, and herbicides.

The centers maintain records of ingredients of trade-name products plus antidotes. This information is available to physicians by telephone day or night. Parents who call the centers are given first-aid instructions and are advised to call their doctor. Poison-control centers are now spread throughout 48 states (all except Vermont and Montana), the District of Columbia, Panama Canal Zone, Virgin Islands, and Guam.

The Hazardous Substances Labeling Act, when in full operation, should facilitate the work of the poison-control centers. The new law, enacted by Congress last year and administered by the Food and Drug Administration, requires that safety information be given on labels of household chemical products, including the identity of hazardous ingredients, antidotes for toxic substances, and warnings and precautions needed for safe use. The law is now fully enforceable with regard to highly toxic and flammable substances. Requirements for labeling other hazardous articles are scheduled to go into effect February 1, 1962.

Under the new law some of the information now available only through the poison-control centers will be required on labels. This, however, will not reduce the need for the medical consulting services supplied by the centers. Many accidental poisonings are caused by consumers' disregard of label information, or by unlabeled substances and, most frequently, by leaving hazardous articles within the reach of small children. It has been estimated that annually 600,000 children swallow household aids left within their reach and that about 500 die as a result.

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(Copied from September 9, 1961 Issue of J.A.M.A.)