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AMERICAN PETROLEUM INSTITUTE
MEDICAL ADVISORY COMMITTEE
28TH MEETING
9:00 A. M.
Monday, November 9, 1959
Conrad Hilton Hotel
Chicago, Illinois

MEMBERS PRESENT:

V. C. Baird, M. D., Chairman
J. W. Osborn, M. D., Vice Chairman
C. R. Miller, M. D., Secretary

W. O. Armstrong, M. D.
C. H. Baylor, M. D.
R. G. Birrell, M. D.
F. F. Boys, M. D.
L. E. Curtis, M. D.
Kieffer Davis, M. D.
R. E. Eckardt, M. D.
T. M. Frank, M. D.
J. H. Hege, M. D.
R. Emmet Kelly, M. D.
T. J. Kelly, M. D.
B. S. Miller, M. D.
B. B. Reeve, M. D.
J. C. Ruddock, M. D.
George M. Saunders, M. D.
Ralph Schneider, M. D.
(Rep. by N. J. Roberts, M. D.)
W. W. Stewart, M. D.
Leo J. Wade, M. D.

TECHNICAL ADVISORS PRESENT:

E. W. Adams
W. H. Barcus
B. E. Bennison, M. D.
C. T. Brown
G. H. Collings, Jr., M. D.
E. K. Daniels
A. E. Dooley
Geo. Entwistle
P. D. Halley
J. W. Hammond
N. V. Hendricks
J. H. Johnston
P. K. Kuhne
C. A. Neilson
A. C. Pabst
T. B. Rendel
L. E. Renes
F. J. Sanders (Rep. by W. E. Scovill)
J. A. Spence
G. M. Wilkening

MEMBERS ABSENT:

R. M. Adams, M. D.
Richard Call, M. D.
J. W. Crookshank, M. D.
K. R. Fourcher, M. D.
F. D. Gassaway, M. D.
E. K. Linder, M. D.
E. P. Luongo, M. D.
T. H. Mitchell, M. D.
R. C. Page, M. D.
R. J. Potts, M. D.

OTHERS PRESENT:

L. E. Carvue - Carter Oil Company
J. C. Colandra - BioTest Labs
Philip Drinker - Harvard University (Consultant)
W. W. Hitchcock - Sinclair Refining Company
Harry Levin - Texaco Incorporated
D. T. Staples - Tidewater Oil Company (Chairman, Medical and Health Committee)

I. INTRODUCTION OF NEW MEMBERS AND GUESTS

Dr. V. C. Baird introduced new members and guests.

II. APPROVAL OF MINUTES

The chairman asked if there were any corrections or additions to the minutes of the 27th meeting of the Medical Advisory Committee, held April 27, 1959, in Chicago.

ACTION: It was regularly moved, seconded, and unanimously passed that the minutes be approved as distributed.

III. CERTIFICATE OF APPRECIATION

Mr. D. T. Staples, chairman of the Medical and Health Committee of the Board of Directors, presented a Certificate of Appreciation to B. B. Reeve, M. D. of the Standard Oil Company (Indiana).

Dr. Reeve responded with a brief history of the origin and early activities of the Medical Advisory Committee.

IV. SUBCOMMITTEE REPORTS

A. Operating Subcommittee

Dr. Clark Miller presented the report of the Operating Subcommittee, reviewing the various recommended actions. This report is attached as Appendix A.

ACTION: It was regularly moved, seconded, and unanimously passed that the actions of the Operating Subcommittee be approved and their report be accepted.

B. Program

In the absence of E. K. Linder, M. D., chairman of the Program Subcommittee, Leo J. Wade, M. D. presented the report for this group. Next year the Industrial Hygienists have been asked to prepare the program for the round table discussion.

ACTION: It was regularly moved, seconded, and unanimously passed that the report of the Program Subcommittee be accepted.

C. Atmospheric Pollutants

Chairman J. C. Ruddock, M. D. reported on the activities of his subcommittee. The minutes of his subcommittee are attached as Appendix B.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

D. C_9 - C_{12} Aromatics

Kieffer Davis, M. D., chairman, reported on the activities of this group. A copy of the report is attached as Appendix C.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

E. Carcinogenicity

R. E. Eckardt, M. D., chairman, reported on this committee's activities. His report is attached as Appendix D.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

F. Dermatology

Leo J. Wade, M. D., chairman, reported on this group's activities. His report is attached as Appendix E.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

G. Epidemiology

George M. Saunders, M. D., chairman, reported on this newly formed subcommittee. His report is attached as Appendix F.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

H. Inhalation of Oil Mist

B. E. Bennison, M. D., chairman, reported on this newly formed group. His report is attached as Appendix G.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

I. Medical Policies and Administrative Practices

In the absence of Ralph Schneider, M. D., chairman of the subcommittee, George M. Saunders, M. D. reported for the activities of this group. Dr. Saunders' report is attached as Appendix H.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

J. Physical Agents

J. H. Hege, M. D., who was appointed chairman of this group to replace C. H. Hine, M. D. who resigned, reported on the activities of this subcommittee. His report is attached as Appendix I.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

K. Specialty Petroleum Products

J. W. Osborn, M. D., chairman, reported on the activities of this group. His report is attached as Appendix J.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

L. Toxicological Reviews

B. E. Bennison, M. D. reported for H. W. Gerarde, M. D., chairman of this subcommittee. The report of this subcommittee is attached as Appendix K.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

M. Industrial Hygiene

J. A. Spence, chairman of the Subcommittee on Industrial Hygiene, reported on the activity of this group. The report includes the activities of the ASA representatives on Sectional Committees Z-4, Z-37, and Z-62. The report of this subcommittee is attached as Appendix L.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

V. REPORT OF LIAISON MEMBERS

A. Dermatology Studies

Leo J. Wade, M. D. stated that there was no activity to report.

B. Smoke and Fumes

J. C. Ruddock, M. D. reported on the activities of the Division of Refining's Smoke and Fumes Committee. His report is attached as Appendix M.

C. American Medical Association

J. W. Osborn, M. D. reported on the activity of the AMA Committee on Toxicology and the Interdivisional Committee on Labeling in the development of proposed legislation on hazardous substances labeling. His report is attached as Appendix N.

D. Interdivisional Committee on Labeling

C. H. Baylor, M. D. reported for C. H. Hine, M. D. who has resigned. His report is attached as Appendix O.

E. First Aid Training

T. M. Frank, M. D. reported on the activity of the Subcommittee on First Aid of the Central Committee on Accident Prevention.

F. Wax Committee

R. E. Eckardt, M. D. reported on the activity of the Advisory Committee to the Wax Research Project. His report is attached as Appendix P.

G. Quarantine Service

George M. Saunders, M. D. reported on this activity. His report is attached as Appendix Q.

H. Petroleum Food Additives

L. E. Curtis, M. D. reported on the activities of this group. Dr. Curtis distributed an Industrial Hygiene Bulletin, prepared by his company, a copy of which is attached as Appendix R.

VI. BUDGET FOR 1960-61

C_9 - C_{12} Aromatics	$10,000
Kerosine Poisoning	12,500
Toxicological Reviews	5,000
Noise	2,500
Consultant	3,000
Administrative Expenses	1,000
Total	$34,000

ACTION: It was regularly moved, seconded, and unanimously passed that the proposed budget be presented to the Medical and Health Committee

VII. NEW BUSINESS

A. Reception for B. B. Reeve, M. D.

Dr. Baird called on Paul Halley who invited all members of the Medical Advisory Committee, subcommittee members, technical advisors, and guests to a reception given in the honor of B. B. Reeve, who will be retired early next year.

B. World Congress

Leo J. Wade, M. D. spoke on the need of supporting the World Congress on Occupational Medicine, which will be held in New York in July 1960.

C. Air Pollution

Prof. Philip Drinker indicated that any information he obtains on air pollution will be sent to the API staff in New York for distribution to the Medical Advisory Committee and its technical advisors.

VIII. NEXT MEETING

The desirability of having the next meeting of the Medical Advisory Committee and its subcommittees in conjunction with the Industrial Medical Association Conference, in Rochester, New York, was discussed.

ACTION: It was regularly moved, seconded, and unanimously passed that the next meeting of the Medical Advisory Committee and its subcommittees be April 22nd through 25th, 1960 in Rochester, New York

IX. CONCLUDING REMARKS BY CHAIRMAN

Dr. Baird adjourned the meeting, stating his appreciation of the great value of Mr. E. O. Mattocks to the Medical Advisory Committee and its activities.

Approved:
V. C. Baird, M. D., Chairman
12/28/59

J. W. Hammond, Recorder

MINUTES OF MEETING
OPERATING SUBCOMMITTEE OF THE MEDICAL ADVISORY COMMITTEE

6:00 P. M.
Sunday, November 8, 1959
Conrad Hilton Hotel
Chicago, Illinois

THOSE PRESENT:

V. C. Baird, M. D., Chairman
J. W. Osborn, M. D., Vice Chairman
C. R. Miller, M. D., Secretary
L. E. Curtis, M. D., Past Chairman

B. E. Bennison, M. D.
Kieffer Davis, M. D.
R. E. Eckardt, M. D.
H. W. Gerarde, M. D.
(Rep. by B. E. Bennison, M. D.)
J. H. Hege, M. D.
E. K. Linder, M. D.
(Rep. by L. J. Wade, M. D.)
J. C. Ruddock, M. D.
Ralph Schneider, M. D.
(Rep. by N. J. Roberts, M. D.)
G. M. Saunders, M. D.
Jack Spence
Leo J. Wade, M. D.

VISITORS:

J. W. Hammond
E. O. Mattocks

I. INTRODUCTORY REMARKS

V. C. Baird, M. D., Chairman of the Medical Advisory Committee and the Operating Subcommittee, announced that Ralph Schneider, M. D. had requested N. J. Roberts, M. D. be his alternate.

II. APPROVAL OF MINUTES

ACTION: The minutes of the April 25, 1959 meeting of the Operating Subcommittee were approved as distributed.

III. REPORT OF SUBCOMMITTEES

A. Program

Leo J. Wade, M. D. reported, in the absence of E. K. Linder, M. D., Chairman. He indicated that the Industrial Hygienists have been invited to conduct the round table session at the next meeting.

B. Atmospheric Pollutants

J. C. Ruddock, M. D., Chairman, discussed possible financial arrangements to continue the work being done by Dr. Goldblatt in England. There still remains $6,155.85 from the original $20,000 raised by the Division of Refining to support the work on the study of the medical aspects of air pollution. Dr. Ruddock explained that Dr. Goldblatt would be willing to continue his study for another year if provision could be made to pay his expenses for travel, possibly to the United States and to other places, and other incidental expenses. The committee was of the opinion that if $5,000 were made available to Dr. Goldblatt for travel expenses, this arrangement would be satisfactory. It was further agreed that no time limit should be placed on the expenditure of $5,000.

Dr. Ruddock discussed the policy of distributing information to the Medical Advisory Committee members and technical advisors. He questioned whether any member of the Medical Advisory Committee should be permitted to submit to the API staff material for distribution to the Medical Advisory Committee members without having the material first reviewed by the chairman of the appropriate subcommittee. There was violent objection to this procedure. It was pointed out that if a subcommittee chairman seriously objected to any distributed material, he could write a letter to the members indicating his objection. It was agreed generally that it was the responsibility of each member of the Medical Advisory Committee to bring to the attention of the other members any data or articles in which he thought the members would have an interest.

C. C_9 - C_{12} Aromatics

Kieffer Davis, M. D. reported that his subcommittee had hoped that this project would be completed by July 1, 1960. However, the work on monkeys will require an extension of time. They recommended that the budget provide $10,000 for the continuation of the work to December 31, 1960.

Dr. Davis requested that, if possible, more members be assigned to this subcommittee.

D. Carcinogenicity

R. E. Eckardt, M. D. reported that their subcommittee had no budget request. The final report from Kettering Laboratory on their work had just been received by the subcommittee members. Dr. Eckardt requested that the report be distributed to the Medical Advisory Committee members and technical advisors and they be requested to submit any comments they have to Dr. Eckardt prior to the subcommittee meeting with Kettering. The comments should be submitted prior to January 1, 1960.

Dr. Eckardt questioned whether the scope of the Subcommittee on Carcinogenicity should be broadened to take into consideration carcinogenicity of other petroleum products, the inhalation of mists, and a review of literature on this subject for possible inclusion in a new scope. Dr. Eckardt asked to be relieved as chairman of this subcommittee. It was agreed that at the next subcommittee meeting they would consider the following: an enlarged scope, possible need to change the name of the subcommittee, and a suggested reconstituted subcommittee.

E. Dermatology

Leo J. Wade, M. D., chairman of this subcommittee, reported on the survey he had conducted on "creeping eruption" in the Louisiana area. His group had concluded there is no major problem. They need more information before any recommendation could be made.

F. Epidemiology

No comment

G. Inhalation of Oil Mist

No pressing question on policy.

H. Medical Policies and Administrative Practices

G. M. Saunders, M. D. reported for Ralph Schneider, M. D. This subcommittee is planning a study of back injuries.

I. Physical Agents

J. H. Hege, M. D., Chairman, indicated that his subcommittee thought that the API should continue its contribution to Dr. Glorig for the study of noise. His group recommended that if any money could be made available that the API contribution should be continued.

Dr. Hege reported that Title 20 of the Atomic Energy Commission Regulations was to be discussed at a public hearing. His group recommended that the API develop a statement, if at all possible, to be read at the hearing. It was generally agreed that the Medical Advisory Committee members should be notified of any such hearing in order that their companies could be present and submit a statement, if the company thinks it is desirable.

J. Specialty Petroleum Products

J. W. Osborn, M. D., Chairman, reported on the activities of their three grant-in-aid projects studying the method of treating kerosine poisoning. Dr. Osborn indicated the need to increase their suggested budget from their previous recommendation of $7,500 to $10,000. This was necessary since the blood analysis previously being run by Horace Gerarde, M. D., Esso Research & Engineering Co., now will have to be run by the universities.

The desirability of discontinuing the work being done by Dr. Nau, University of Texas, was reviewed carefully.

K. Toxicological Reviews

B. E. Bennison, M. D. reported for H. W. Gerarde, M. D. and indicated that they had no problems.

L. Industrial Hygiene

Jack Spence stated that the liaison members to the ASA Sectional Committees would now make their report directly to the Industrial Hygiene Subcommittee.

IV. 1960-61 BUDGET

The following was suggested for the new budget:

C_9 - C_{12} Aromatics	$10,000
Kerosine Poisoning	12,500
Toxicological Reviews	5,000
Noise	2,500
Consultant	3,000
Administrative Expenses	1,000
Total	$34,000

ACTION: It was regularly moved, seconded, and unanimously passed that the above distribution for Medical Advisory Committee budget of $34,000 be recommended to the Medical Advisory Committee for transmittal to the Medical and Health Committee.

V. CERTIFICATE OF APPRECIATION

V. C. Baird pointed out the desirability of establishing a permanent Certificate of Appreciation Subcommittee who would have the responsibility of automatically recommending nominees to receive Certificates of Appreciation.

ACTION: It was regularly moved, seconded, and unanimously passed that a permanent Certificate of Appreciation Subcommittee be appointed, composed of the current chairman, vice chairman, secretary of the Medical Advisory Committee, plus any active past recipients of Certificates of Appreciation until such time as there are at least three active past recipients who will then become the permanent subcommittee.

VI. PUBLICITY

The desirability of securing greater publicity of the activities of the Medical Advisory Committee was reviewed. The last issue of the Department of Technical Services Newsletter contained several items on the activities of the Medical Advisory Committee. The group, in general, thought this was very good. They did not believe, however, that the activities of this group should be publicized too extensively.

The desirability of transmitting to the Medical Advisory Committee and technical advisors the official transcript of the joint meeting which the Subcommittee on Atmospheric Pollutants had with the Public Health Service in Cincinnati, was discussed.

ACTION: It was regularly moved, seconded, and unanimously passed that the transcript of the joint meeting of the Subcommittee on Atmospheric Pollutants with the Public Health Service should be transmitted to the Medical Advisory Committee and its technical advisors and the Smoke and Fumes Committee.

VII. SUBCOMMITTEE CHAIRMEN

It was generally agreed that the technical advisors as well as members of the Medical Advisory Committee may become chairman of subcommittees.

ACTION: It was regularly moved, seconded, and unanimously passed that technical advisors to the Medical Advisory Committee can properly become chairman of a subcommittee of the Medical Advisory Committee.

VIII. MAC MEMBERSHIP

With the recent consolidation of subsidiaries into a parent company, the question of the definition of a member on the Medical Advisory Committee was discussed. The API Board of Directors, at their April 21, 1954 meeting, defined members of the Medical Advisory Committee as follows: "Physicians nominated by petroleum companies, and appointed annually by the Chairman of the Medical and Health Committee. These physicians may be employed by petroleum companies either full-time, part-time, or as consultants."

After reviewing this definition, it was the opinion of the Operating Subcommittee that the definition was adequate as it was written by the Board of Directors and did not confine membership from one company to a single physician.

ACTION: It was regularly moved, seconded, and unanimously passed that the Operating Subcommittee's interpretation of the Board of Directors' definition of Members to the Medical Advisory Committee provided for any number of physicians from a single company.

IX. NEW BUSINESS

A. Air Pollution Committee

A letter received from Richard A. Prindle, M. D., Chief of the Air Pollution Medical Program, Division of Special Health Service of the Department of Health, Education, and Welvare, dated October 28, 1959, to E. O. Mattocks, indicated that they had formed an Air Pollution Committee which is a technical task group on auto exhaust studies. This committee was formed by the Public Health Service for the purpose of assisting in the coordination of research activities in furthering cooperation between interested groups involved in the studies of automobile exhaust air pollution. Mr. William Clausen represents the API on this committee, having been appointed by Dr. Jerry McAfee, Chairman of the Smoke and Fumes Committee of the Division of Refining.

ACTION: It was regularly moved, seconded, and unanimously passed that the Medical Advisory Committee should inform Mr. William Clausen that this group stands ready to offer to him any service possible in the performance of his duty as a member of the Air Pollution Committee.

B. Visitors

Dr. Baird indicated that he had asked Dr. Franklin Youder and Dr. B. Dixon Holland of the American Medical Association to attend the Medical Advisory Committee meeting. Also, Dr. Colandra, who did consulting service for Sinclair, had been invited to attend the MAC meeting.

ACTION: It was regularly moved, seconded, and unanimously passed that the action of the chairman in inviting the three doctors to attend the MAC meeting be approved.

C. Division of Refining's Smoke and Fumes Committee API 07542

Dr. Ruddock stated that he had been invited to appear before the Division of Refining's Smoke and Fumes Committee and give a report of his Subcommittee's activities. Dr. Ruddock asked if there were any objections to his appearing before this committee.

ACTION: It was regularly moved, seconded, and unanimously passed that Dr. Ruddock should accept the invitation to appear before the Division of Refining's Smoke and Fumes Committee.

D. Dr. Malcolm Hargraves

Possible ways of presenting information on the petroleum industry to Dr. Malcolm Hargraves, of the Mayo Clinic, were reviewed. It was indicated that Dr. Roberts was a former member of the Mayo Clinic and could possibly help. The staff was directed to collect all of the material relating to Dr. Hargraves' published statements on the petroleum industry and transmit them to Dr. Roberts for his review.

It was indicated further that Dr. Carl Nau of the University of Texas would be very helpful in presenting facts to Dr. Hargraves.

X. NEW MAC OFFICERS

It was generally agreed that J. W. Osborn, M. D. should be recommended for appointment to the chairmanship of the Medical Advisory Committee. It was further agreed that the new chairman, together with the staff and what other assistance he may chose, should recommend to the chairman of the Medical and Health Committee the new slate of officers. The possibility of two vice chairmen was briefly discussed.

E. O. Mattocks, Recorder

Approved:
V. C. Baird, M. D., Chairman
12/28/59

REPORT OF SUBCOMMITTEE ON ATMOSPHERIC POLLUTANTS
John C. Ruddock, M. D., Chairman

MINUTES
SUBCOMMITTEE ON ATMOSPHERIC POLLUTANTS
9:00 A. M.
Friday, November 6, 1959
Conrad Hilton Hotel
Chicago, Illinois

The meeting was called to order by the chairman at 9:00 A. M. There were six members of the subcommittee present and 15 visitors.

Minutes of the last meeting, held on September 22, 1959, at the Sheraton-Gibson Hotel in Cincinnati, Ohio, were approved as presented.

DISPOSITION OF GOLDBLATT REPORT

A discussion, which considered publishing the report in book form for general distribution, was carried on by the subcommittee, as well as the possibility of publishing this report by USPHS; finally it was unanimously approved that the matter be tabled until after the entire report had been received and reviewed by the subcommittee. Publication should not be done in its present form but be edited by the author prior to publication.

Continuation of Project MC-4 by Dr. Goldblatt was passed by this subcommittee on two previous occasions. Since the meeting of September 22, 1959, Dr. Goldblatt has been offered $5,000 which he refused as a fee, but accepted if this amount was offered for an expense account. It was suggested by Mr. Mattocks that the unused portion ($6,100) of the original grant be used to continue the study. This was moved, seconded, and approved.

The chairman also read a letter from Dr. Prindle, of the USPHS, in which Dr. Prindle indicated that the USPHS would accept an application for a grant to Dr. Goldblatt to continue his work as already started by the API, as a critical clinical survey of the world's medical literature on air pollution. The subcommittee felt that this is a matter between the USPHS and Dr. Goldblatt. It was felt that application forms should be forwarded to Dr. Goldblatt for submittal and that his work be continued as presently stated. There are three more portions of this report yet to be received.

The matter of distribution of reprints and public articles through the various committees was discussed and referred to the Operating Subcommittee.

DISCUSSION OF COMMUNICATIONS WITHIN INDUSTRY, COMPANIES, AND INDIVIDUALS

Mr. Mattocks explained that before a statement is released by the API that it must have the O.K. from the Medical and Health Committee of the Board of Directors and a substantial unanimity on the matter from its main members by letter ballot. When such is not obtained, then a public release is not made.

CALIFORNIA AIR QUALITY AND AUTO EXHAUST EMISSION STANDARDS

Tentative standards, which will be adopted into law in February 1960 in California, on air quality were presented and have been circulated to all members of the MAC.

Tentative auto exhaust standards were presented as follows:

Hydrocarbon reduction from 1600 ppm to 275 ppm
Carbon monoxide reduction from 3.8 wt. % to 1.5 wt.%

JOINT MEETING WITH THE USPHS (BOTH MEDICAL AND TECHNICAL), AUTOMOBILE MANUFACTURERS ASSOCIATION (WITH REPRESENTATIVES FROM GENERAL MOTORS, FORD, AND CHRYSLER), RAILROAD ASSOCIATION, MEMBERS OF SUBCOMMITTEE, AND OTHERS

It was the general opinion of those persons attending this meeting that it was interesting and worthwhile, especially because it gave all interested parties in Air Pollution Abatement a chance to be heard and exchange ideas and work together toward a common goal. Such a meeting, the first of its kind, should be held every two years. A certified report of the meeting will be circulated to members. Please read it as it is a documented report of statements by AMA, Public Health, Railroad Association, and others.

Meeting adjourned at 11:15 A. M.

John C. Ruddock, M. D. Chairman
Subcommittee on Atmospheric
Pollutants

REPORT OF SUBCOMMITTEE ON C_9 - C_{12} AROMATICS

Kieffer Davis, M. D., Chairman

The Subcommittee on C_9 - C_{12} Aromatics met at 2:00 P. M. November 6, 1959 at the Conrad Hilton Hotel.

Members present - Dr. Frank
Mr. Spence
Mr. Hammond
Dr. Davis

Members absent - Dr. Crookshank
Dr. Potts
Mr. Bent

Some twenty guests were present.

Dr. Nau, the chief investigator, reviewed a previously submitted progress report to the subcommittee. The major features of this report were:

I. Work completed:

(1) Rat inhalation studies at 3.2 mg/liter for the four chemicals, N-Decane, C_9 - C_{10} aromatics, C_{11} - C_{12} aromatics, and benzene.

(2) Rat inhalation studies at 200 ppm for the three chemicals, C_9 - C_{10}, C_{10} - C_{11}, and benzene.

(3) Rat inhalation studies at 50 ppm for the two chemicals, C_9 - C_{10} and benzene.

(4) Determination of LC_{50} values on rats for the three chemicals, C_9 - C_{10}, C_{11} - C_{12}, and benzene for one 7 hour exposure.

(5) Cellular study of the bone marrow of rats exposed by inhalation to N-Decane, C_9 - C_{10}, C_{11} - C_{12}, and benzene.

II. Significant Findings Not Previously Reported Are:

(1) There are significant hematological findings in rats exposed 18 hours a day to the inhalation of 3.2 mg per liter of C_9 - C_{10}, C_{11} - C_{12}, and benzene, but not in rats exposed for the same period of time and concentrations of N-Decane vapors.

(2) LC_{50} for rats shows the increasing order of toxicity as follows: (1) benzene, (2) C_9 - C_{10}, and (3) C_{11} - C_{12}.

(3) A large number of rats develop cataracts after being exposed to high concentrations of C_9 - C_{10} vapors, and a lesser concentration of benzene.

(4) Preliminary work on monkeys indicates exposure to 200 ppm of C_9 - C_{10} vapors causes significant effects.

III. Recommendations For Continuation Of Work:

(1) Expose monkeys to test materials at 50 ppm and 200 ppm for an adequate length of time.

(2) Determine the threshold of odor and tolerance for humans to the test materials.

(3) Complete all test studies now in progress and prepare a final report.

It is anticipated by the subcommittee that this experimental project will be ended on or about the first of the year 1961.

Accordingly, it is recommended that additional funds in the amount of $10,000 be appropriated for the continuance of the program to its completion.

Kieffer Davis, M. D., Chairman
Subcommittee on C_9 - C_{12} Aromatics

APPENDIX D-1

REPORT OF SUBCOMMITTEE ON CARCINOGENICITY

R. E. Eckardt, M. D., Chairman

1. The final report of the Kettering Laboratory was not received in sufficient time by the subcommittee to be reviewed prior to its meeting on November 7, 1959. It is the plan of the subcommittee, therefore, to review this report with the Kettering Laboratory and submit it, or a finalized version, to the Medical Advisory Committee at its April, 1960 meeting.

2. In the meantime, the subcommittee will circulate the report as received from the Kettering Laboratory to the members and technical advisors of the Medical Advisory Committee, in order to receive their comments, before holding a final discussion with the Kettering Laboratory, probably sometime in late January or early February.

R. E. Eckardt, M. D., Chairman
Subcommittee on Carcinogenicity

APPENDIX E-1

REPORT OF SUBCOMMITTEE ON DERMATOLOGY
Leo J. Wade, M. D., Chairman

MEMBERS PRESENT: Leo J. Wade, M. D., Chairman
Curtis Baylor, M. D.
Allan Dooley
James Osborn, M. D.

GUEST: L. E. Curtis, M. D.

On February 9th, Chairman Baird requested this subcommittee to investigate a report submitted by an unidentified Louisiana physician that "creeping eruption" is an increasingly important occupational health hazard for petroleum production workers along the Gulf Coast. The letter implied the need for financial aid to investigate the alleged problem.

The Dermatology Subcommittee circularized the members of the Medical Advisory Committee seeking information re the magnitude of the skin complaint among petroleum workers.

The results were as follows:
10 - No producing operations in area
14 - Producing operations in area
11 - No knowledge of any cases
3 - Aware of few cases
(Cities Service,
Standard Oil (Ohio), Humble)

Dr. Crookshank of Cities Service indicated some limited experience with the problem but indicated that he had "a great deal of information" re the situation. No replies have been received to two subsequent letters to Dr. Crookshank.

Dr. Osborn of Standard Oil (Ohio) had two possible cases reported to him by local physicians. Follow-up letters to these physicians for additional information have not been answered.

Dr. Wise of Humble reported two cases but none within the past year. These were seen by Dr. Rodney Jung, Associate Professor of Tropical Medicine, Tulane University. His associate, Dr. James Burks, is preparing a manuscript for presentation at the next Southern Medical Association meeting. He has promised to send a copy of the manuscript as soon as it is completed.

Your subcommittee reports, therefore, that its investigation is incomplete but will continue. Findings to date suggest a relatively minor problem affecting only a few members of the API. We have no immediate recommendations.

The subcommittee stands ready to accept other assignments as desirable.

Leo J. Wade, M. D., Chairman
Subcommittee on Dermatology

REPORT OF SUBCOMMITTEE ON EPIDEMIOLOGY

Geo. M. Saunders, M. D., Chairman

I INTRODUCTION

An ad hoc Subcommittee on Epidemiology in a report to the MAC on 10 November 1958 defined epidemiology as a method of study and recommended again that a standing Subcommittee on Epidemiology be appointed. At a meeting on 27 April 1959, the MAC authorized the creation of such a Subcommittee and by letter of 15 June 1959, the Chairman of the MAC to the present Chairman of the Subcommittee on Epidemiology requested that he propose names for membership on the Subcommittee. This was done and a Subcommittee of four members, including the Chairman, was formed. The members have been in frequent communication and a meeting to draft recommendations for future studies was held on 11 August 1959.

As a background, it is pertinent to quote from the report of the former ad hoc Subcommittee which stated:

> "Epidemiology is the study of the occurrence of qualities, conditions, diseases and deaths as mass phenomena among groups of people."

It was emphasized that for any studies to have statistical validity, the events or conditions being observed and recorded be susceptible of clear definition and be related to a population group whose other characteristics are known. In other words, if the number of events tabulated is the numerator of a fraction, then the denominator must also be known in order to be meaningful. To carry this one step further, the element of time must be introduced if rates of occurrence of events are to be calculated.

It is recognized that there may be certain health problems which are more or less limited and unique to the petroleum industry but it is felt that epidemiologic studies should not be limited to these unique problems. Health records on employee groups, particularly in many units of the petroleum industry, constitute an important source of valuable information upon the health level of the "normal" and "well" population. It is felt that where practical such information should be brought to light and critically examined.

This present report will present general principles of methods of operation needed to collect valid data, will list areas for possible future study which may be productive and will recommend certain specific conditions or areas for present pilot studies.

II METHOD OF OPERATION

It has already been suggested that it is necessary to have an accurate reporting of events or characteristics or qualities or conditions occurring in any given unit of time in a limited group of employees. To accomplish this will require not only the cooperation but also the active participation of medical department personnel in units of many oil companies where the medical observations and records are suitable

to the purpose and where the population at risk is known. Reporting to the Subcommittee must be in a uniform, standard way.

As an example, let us consider that it is recommended by the MAC that a study be made of the frequency of myocardial infarction among refinery maintenance and operating personnel (blue collar workers) to compare with the frequency of this condition among refinery office workers such as engineers and laboratory workers (white collar workers).

In order to collect meaningful data, it would be necessary to have a standard system of reporting from a number of refinery medical units volunteering to participate in the study. The criteria for diagnosis must be standardized and the population at risk must also be defined as to job category, age, length of service, and in other ways to be determined. Reports would be requested periodically on the number of cases occurring in each participating group over a period of time to be determined by the study group in order that the frequency of occurrence of the condition could be stated in terms of person-years of of risk by age and job. Data from reporting on a predetermined standard form would be coded for transfer to punch cards for analysis and tabulating.

III SUGGESTED AREAS FOR FUTURE STUDY

Among the many conditions which were considered as possibly providing valuable information, the following may be listed:

A. Mortality Rates
   Age specific rates by cause.
   Age specific crude mortality rates.

B. Health Status of Truck Drivers
   Sampling survey to include a record of age, length of service, present physical status and disqualifying conditions, if any.

C. Study of Blood Pressure Levels
   By age, height, weight, job category and length of service.

D. Chest X-Ray Findings in Refinery Maintenance Workers
   By age, length of service, etc., to compare with group of office workers.
   There has been some suggestion that there is an increased risk of pneumoconiosis among refinery maintenance workers.

E. Hematological Studies on Refinery Workers Exposed to Aromatics with Studies on a Control Group

F. The Incidence of Lung Cancer Among Selected Groups

G. Results of Proctoscopic Examinations

H. Absenteeism

I. Radiation Exposure Related to Evidence of Physiologic Effects

These and many others might be listed as potentially valuable subjects for investigation. However, the various areas to be explored should be recommended and authorized by the MAC as a whole with the voluntary and active collaboration of suitable units within the numerous companies. At present it is believed that no request for an operating budget is in order. However, if pilot studies to be proposed prove valuable and productive, then funds may be required in the future.

IV PROPOSAL FOR SPECIFIC STUDIES

As preliminary pilot studies to explore the practicality of conducting meaningful epidemiological investigations through the MAC, two studies are proposed:

A. The Frequency of Myocardial Infarction

B. The Health Status of Truck Drivers

The methods and procedures will be defined in a protocol if collaboration of suitable medical units is assured. The first study will require a reporting of all cases of myocardial infarction among known population units over a given period of time. The second will require the reporting on a standard form to be devised results of the most recent examinations of truck drivers.

Subcommittee on Epidemiology
George M. Saunders, M.D., Chairman
C. H. Baylor, M.D.
B. E. Bennison, M.D.
N. V. Hendricks

REPORT OF SUBCOMMITTEE ON INHALATION OF OIL MISTS

B. E. Bennison, M. D., Chairman

1. Following the authorization of this Subcommittee at the Spring MAC Meeting, replies were invited from members or technical advisors who had an interest in serving on this Subcommittee. Additional suggestions for membership will be welcome.

2. The published literature and certain documented company experiences have been assembled for critical review. It is apparent that there are a number of important areas that merit the attention of this Subcommittee. Two examples may be mentioned:

    a. The oil mist levels that occur around certain large-scale machine shop operations.

    b. The increasing agricultural use of oil sprays.

3. It is anticipated that a more detailed progress report of this newest Subcommittee will be available for the next meeting of the Medical Advisory Committee. It is recommended that this report be accepted as a preliminary report.

Respectfully submitted,

/s/ B. E. BENNISON

/s/ B. E. BENNISON, M. D., Chairman

REPORT OF SUBCOMMITTEE ON MEDICAL POLICIES AND ADMINISTRATIVE PRACTICES
Ralph Schneider, M. D., Chairman

1. After further discussion and deliberation at a meeting of the subcommittee on November 7, 1959, it was decided that the "Guiding Principles" is not yet ready for submission to the Medical Advisory Committee.

2. It is recommended to the Medical Advisory Committee that if further investigation on the value of low back X-rays is desired, that the project be referred to the Subcommittee on Epidemiology.

It is moved that this report be accepted.

G. M. Saunders, M. D.
Acting Chairman
Subcommittee on Medical
Policies and Administrative
Practices

REPORT OF SUBCOMMITTEE ON PHYSICAL AGENTS

J. H. Hege, M. D., Interim Chairman

The subcommittee convened on one occasion since the 1958 November meeting, the majority of its business being carried on by correspondence.

The subcommittee has continued, during the past year, to abstract the literature and develop bibliographies on important developments for the various categories of physical agents. These have been circulated to members of the MAC as appropriate.

A progress report has been received from Dr. Glorig in which he described his research activities to include:

1. Effects of intermittant noise exposure on temporary threshold shift.
2. Effects of impulse noise on temporary threshold shift.
3. Study of over 100,000 records to determine the extent of hearing loss in the general population as compared to an industrial population.
4. Preparation of International Standards for specific noises.

Dr. Glorig has requested continued financial support in his research work. The API has, in the past on recommendation of the MAC, granted a total of $12,500 for this purpose. We have been advised that by reason of budgetary considerations, the API Board of Directors has deleted all appropriation for continuation of this project from the 1960-61 MAC budget.

By reason of the circumstances necessitating the directive of the Board of Directors, the subcommittee accedes to their action and recommends to the MAC that a budgetary allowance not be requested for Dr. Glorig's research projects for the year 1960-61. This, however, is not to be construed to indicate a loss of interest in Dr. Glorig's work. The subcommittee is of the opinion that Dr. Glorig's work is both of great importance and unique. Eliminating human considerations, work on noise is of serious import solely on the basis of financial loss to industry. Dr. Glorig's work is unique in that little or none of the work his group is doing has been or is being done by other research groups.

The subcommittee recommends that, if any money budgeted for other MAC activities might be considered to serve a more useful purpose as support for Dr. Glorig's work, permission be secured to transfer an appropriate sum to be awarded as a grant to Dr. Glorig. If this recommendation is not feasible, it is the consesus of the subcommittee that a request for reinstatement of this grant be made by the MAC at the earliest appropriate time.

The subcommittee recommends that the MAC as individuals continue to support Dr. Glorig by providing him with material from plant noise surveys, hearing conservation programs, etc.

On 27 September 1959, AEC Regulations Title 20 promulgating regulatory changes governing the use of radioisotopes was published. Because many objections were made, implementation of Title 20 was delayed pending public hearings. A summary of the objections indicate that industry would have a difficult if not impossible task living under the proposed changes.

The subcommittee, upon notice, will promulgate the date of the public hearings so that those who wish can voice their opinions either as individuals or representatives of their company.

The subcommittee recommends that the MAC call this matter to the attention of the API in event the API wishes to have a representative appear at these hearings in its behalf.

J. H. Hege, M. D., Interim Chairman
Subcommittee on Physical Agents

Addendum:

The Operating Subcommittee at its meeting of 8 November 1959 advised that $2,500 of funds appropriated for the 1960-61 budget is available for use as a grant to Dr. Glorig. The Subcommittee voted to grant this $2,500 to Dr. Glorig for continuation of his research on noise.

/s/ J. H. Hege, M. D.

REPORT OF SUBCOMMITTEE ON SPECIALTY PETROLEUM PRODUCTS

J. W. Osborn, M. D., Chairman

MEMBERS PRESENT:

J. W. Osborn, M. D., Chairman
C. H. Baylor, M. D.
J. W. Hammond
N. J. Roberts, M. D., representing R. F. Schneider, M. D.

GUESTS:

E. W. Adams
R. G. Birrell, M. D.
G. H. Collings, M. D.
A. E. Dooley
Geo. Entwistle
N. V. Hendricks
C. A. Nau, M. D.
Leo Wade, M. D.

Minutes of the special meeting, held October 2, 1959, at Linden and New Brunswick, N. J., were thoroughly reviewed resulting in the following comments and recommendations.

A. CLINICAL RESEARCH AND BLOOD HYDROCARBON ANALYSES

1. Dr. Gerarde has developed a new method for determining the aromatic fraction of hydrocarbons in blood, entitled "A Photoelectric Colorimetric Method for the Determination of Kerosine in Blood." This method is to replace, at once, the original Ultra-Violet Spectrophotometric Analysis Method.

2. Esso Research Center can no longer pefform these analyses for either our research program or the Cooperative Clinical Project under Dr. Edward Press. Drs. Daeschner and McKay will probably prefer to do these analyses in their own laboratories but this will require special training of at least one person in each laboratory. It is possible that a method may be worked out whereby these analyses can be done in some other central laboratory thus reducing costs. Dr. Carl Nau has offered his laboratory as a possible place. The mechanism of this will be worked out in the near future, however, additional funds will be necessary from API sources to pay for these analyses.

3. The subcommittee, therefore, asks the MAC to approve $10,000 for our overall kerosine research program for the fiscal year 1960-61. This is a $5,000 increase to cover this additional expense as needed and possibly to support other observations felt needed in laboratory research if experience in the next six months with the costs of the new test method reveal there will be any balance available within this $10,000. This money is requested as a grant-in-aid. (The Operating Subcommittee on 11/8/59 approved an additional $2,500 to support Dr. Nau's industry research proposal, the work to be done in the summer of 1960.)

B. SUMMARY OF LITERATURE ON KEROSINE POISONING

Dr. Daeschner's summary and annotated bibliography of the available literature on petroleum distillate poisonings is about 90-95% complete, with summaries on 35 articles. Some 8 or 10 other articles, including Dr. Gerarde's "V. Kerosine," just published in September 1959, will be reviewed in the near future. Dr. Carl Nau, whose library is larger, will assist Dr. Daeschner in obtaining the other 8 or 10

articles. The subcommittee expects that this annotated bibliography will be available before next spring's meeting, at which time we expect to make specific recommendations on how it should be distributed.

C. LABORATORY RESEARCH ON KEROSINE

Dr. Nau discussed with the subcommittee a report of the work which he and his staff performed this summer, financed in part by our API grant-in-aid to him of $2,500, entitled "A Study of the Ingestion of Kerosine." He also discussed with us a proposal for further continuation of his experimental work for next summer. His report and proposal will be attached as part of these minutes.

It was the consensus of the subcommittee that due to the financial situation of the API budget, that we should not specifically recommend to the MAC, at this time, positive support for Dr. Nau's proposal. It was felt that if the $10,000 asked for, to make sure that the clinical program did not bog down, turned out to be sufficient to leave a balance for the next fiscal year, that we may wish to use this balance for further support of Dr. Nau's work. During the next six months, sufficient experience should develop regarding the costs of the new method for blood hydrocarbon analysis so that by next spring's meeting the subcommittee should know whether or not there will be any funds available within the $10,000 for the fiscal year 1960-61. (The Operating Subcommittee on 11/8/59 approved an additional $2,500 to support Dr. Nau's industry research proposal, the work to be done in the summer of 1960.)

D. AMERICAN ASSOCIATION OF POISON CONTROL CENTERS

At the personal request of the subcommittee chairman, Dr. B. B. Reeve attended the second annual meeting of this association, at the Palmer House in Chicago on October 6, 1959. A copy of his report, dated October 20th, is attached. Based on Dr. Reeve's report and our discussion, the subcommittee voted to recommend that the Medical Advisory Committee should become a member of this association. Annual dues for a person are only $5.00. The details of this membership can be worked out with the chairman of the MAC, if approved.

E. COOPERATIVE CLINICAL PROJECT WITH EVALUATION OF KEROSINE AND RELATED PETROLEUM DISTILLATE INGESTION

The subcommittee chairman replied on August 14th to Dr. Edward Press, at the American Public Health Association, regarding our decision of last spring not to seek further informal liaison with this project. Our contacts with Dr. Daeschner and Dr. McKay, who are also members of this project, are considered adequate.

The subcommittee chairman will keep in touch with Dr. Press regarding further developments in this project which is certainly not yet ready for publication.

J. W. Osborn, M. D., Chairman
Subcommittee on Specialty
Petroleum Products

Subcommittee Members

Approving	Disapproving
C. H. Baylor	
J. W. Hammond	
N. J. Roberts for R. F. Schneider	

COPY

THE UNIVERSITY OF TEXAS--MEDICAL BRANCH

The School of Medicine
The School of Nursing
The Technical Curricula
The Post-Graduate Program

Galveston

The John Sealy Hospital
The Children's Hospital
The Psychopathic Hospital
The Rosa and Henry Ziegler Hospital

October 6, 1959

James W. Osborn, M.D.
Standard Oil Company
Midland Building
Cleveland, Ohio

Dear Jim:

In accordance with our conversation, I wish herein to make a proposal for further continuation of our experimental work here at the Medical School, said work involving the possible ingestion of kerosene. It is proposed that:

1. Quantitative studies of the amount of kerosene occurring in the various organs under varying conditions and amounts of kerosene administered be done and that efforts be made to correlate such data with gross and microscopic pathological findings. This suggestion is based upon our findings that there is conclusive evidence that damage occurs in the lung, liver, kidney and the heart if and when kerosene is detected in the blood.

2. We will do further studies on radiography in relation to the amount of kerosene that will be administered into the stomach.

3. Further work in autoradiography is contemplated. This would include liquid scintillation counts on the plasma and extraction and deposit on chromatographic paper of the kerosene with subsequent analyses of the amount extracted from the various organs and tissues.

4. Efforts will be made to eliminate rapid transfer of kerosene from the gastro-intestinal tract to the blood through various means.

For this proposal, it is intended to use medical students who have both ability and interest. This would not only accomplish something worthwhile with reference to our study of kerosene but would also be

C O P Y

of some value in recruitment of future industrial physicians. For this proposal, it would be suggested that funds equal to those which were allocated to us last year be provided on the basis identical to that for last year.

I would be happy to supply any other information that you may wish. I find that the radiographic work that was done in this laboratory is new, extremely informative and worthwhile.

I was pleased to have the opportunity of attending our recent meeting at the Esso Laboratories and I am herein sending you my expense account to cover this trip.

Kindest regards.

Sincerely yours,

CARL A NAU, M.D.

CAN/hb

THE UNIVERSITY OF TEXAS — MEDICAL BRANCH
GALVESTON

THE SCHOOL OF MEDICINE
THE SCHOOL OF NURSING
THE TECHNICAL CURRICULA
THE POST-GRADUATE PROGRAM

THE JOHN SEALY HOSPITAL
THE CHILDREN'S HOSPITAL
THE PSYCHOPATHIC HOSPITAL
THE ROSA AND HENRY ZIEGLER HOSPITAL

September 14, 1959

Carl A. Nau, Sr., M. D.
University of Texas Medical Branch
Galveston, Texas

Dear Dr. Nau:

During the past year, Mr. J. DeLeon and Joacquim Marrow have made numerous microsections of organs from rats given 0.3 cc. of kerosine labelled with 10 mc. of radioactive hydrogen (H_3). Autoradiographs have demonstrated kerosine in the following organs and/or spaces:

1) Stomach
2) Plasma
3) Lungs
4) Liver
5) Kidney
6) Bladder
7) Heart muscle

(Only kidney, plasma, and stomach really convincing.)

Even now, many anticipated difficulties have not been surmounted. These include:

1) Microsection preparation, including cutting, mounting, and staining.

2) Exposure and development of special film and emulsion.

RECOMMENDATIONS:

1) That qualitative autoradiography be continued, sharply limiting the number of sections and the methods of processing.

2) That quantitative organ analysis be instituted. Liquid scintillation counting could be employed on plasma; however, color interference would probably introduce too much variability for organ analysis. Extraction and deposit on chromatograph paper would permit analysis on the equipment in the Radiology Isotope Laboratory. This will require considerable precision and knowledge of radiation physics, especially with low energy levels.

Sincerely,

Colvin H. Agnew, M. D.
Department of Radiology

CHA:cks

cc Dr. R. N. Cooley
Dr. L. B. Beentjes

A STUDY OF THE INGESTION OF KEROSENE

Joe deLeon
Joaquin Marron
Carl A. Nau, M. D.
Department of Preventive Medicine and Public Health
University of Texas Medical Branch
Galveston, Texas

For a long period of time there has been a controversy as to whether the pneumonitis associated with or arising out of the ingestion of kerosene is due to the aspiration of the kerosene or whether it is due to the hematogenous transmission of the ingested kerosene to the lungs (and to other organs and tissues). The answer to this question will help determine whether a person who has swallowed kerosene should be lavaged. The Academy of Pediatrics, the American Public Health Association and the American Medical Association presently are conducting a clinical study in an effort to answer the question of how to treat a patient who has ingested kerosene. It is our purpose, by using rabbits, mice and rats, to determine if kerosene is absorbed from the gastro-intestinal tract and if kerosene can be detected in the blood and various organs - such as lung, liver and kidney - after ingestion. It is also our purpose to determine if changes from the normal occur in these organs and tissues where kerosene may be detected.

Material and Methods

For our study we used kerosene furnished by the Humble Oil and Refining Company and having the following specifications:

Test	Limits	Test Method
Gravity, °API	41-44	ASTM D 297
Flash Point, °F, Min.	120	ASTM D 56
Saybolt Color, Min.	25	ASTM D 156
Corrosion, 3 hrs. at 122° F.		
Max. on ASTM scale	1	ASTM D 130
Doctor Test	Sweet	FSM 5203
Burning Test, hours, Min.	24	ASTM D 187
Distillation, °F.		
IBP, Min.	380	
10% Recovered	348-425	
95% Recovered, In.	465	
End. Point, Max.	530	
Sulfur, wt. %, Max.	0.13	ASTM D90

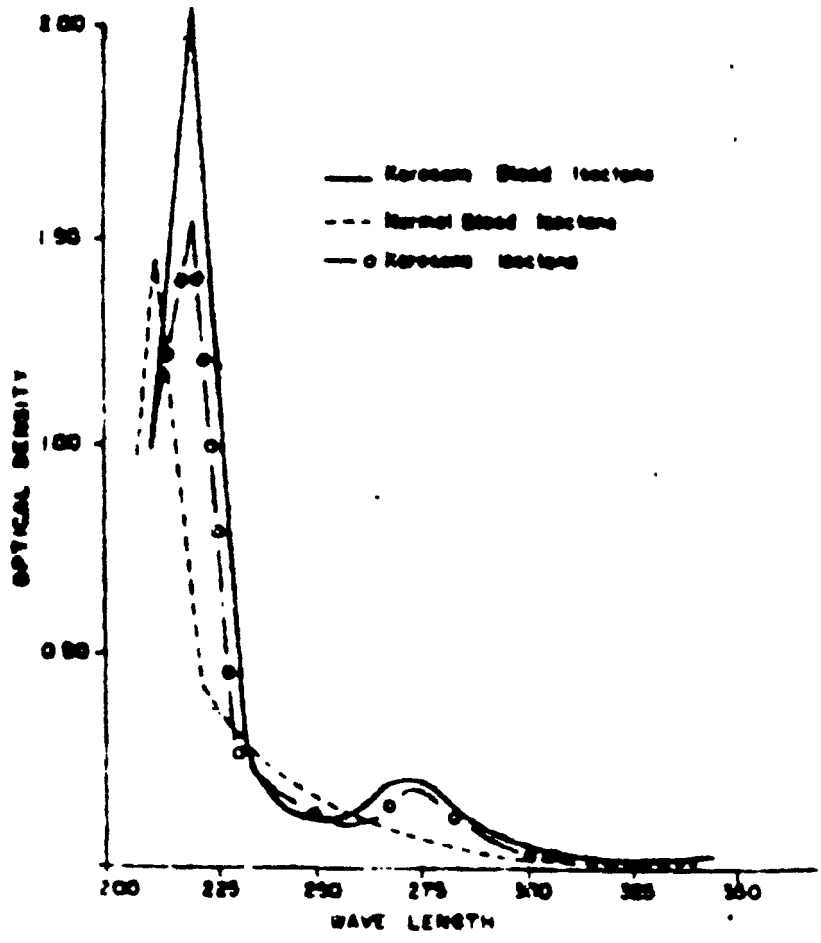
Rabbits, rats and mice were used as test animals. Kerosene was given to rabbits intravenously and by stomach tube in dosage up to 30cc per Kg.; to rats by stomach tube in dosages varying from 5 to 20 cc per Kg.; and to mice in dosages of 0.3 cc each via stomach tube.

The blood was drawn after 3 minutes (or longer) and as long as 24 hours after the administration of the kerosene. When the animals were sacrificed or found dead, a complete pathological evaluation (gross and microscopic) was made.

Since kerosene is miscible in iso-octane, this material (spectro-grade as furnished by the Phillips Petroleum Company) was used as the extracting vehicle. It removes kerosene from blood effectively.

A concentration curve was made for both of the kerosene peaks since it was found that kerosene mixed with iso-octane produces a sharp peak at wave length 221 millimicron, and a slight peak at wave length 273 millimicron when read on a Beckman Model DU Spectrophotometer. The extracted sample was read from wave length 209 millimicron through wave length 400 millimicron using the ultraviolet light.

Both positive as well as negative "control bloods" were read. (See figure below). An equal volume of blood and iso-octane were used for 4 minutes of extraction.



Large dosages of kerosene were employed in rabbits and rats; comparable doses in man would have been beyond what one might expect a person to consume. Therefore, it was decided to have kerosene labelled with radio-active tritium by the New England Nuclear Corporation and to use autoradiography to demonstrate gastrointestinal absorption and cellular deposition of this radioactive material given in minute doses to mice. Autoradiographic permeable base stripping film (emulsion No. J8-1906) and permeable base emulsion (NTB_2) were furnished by the Eastman Kodak Company for our use.

Thirty mice, starved for 12 hours, were anesthetized using sodium amytal intraperitoneally. An incision was made below the left costal arch from the xiphoid process to the posterior axillary fold. The exposed muscle was cut carefully with sharp scissors and the stomach and lower end of the oesophagus were exposed. A ligature was passed under the oesophagus and tied carefully thus insuring that no radioactive kerosene could be regurgitated and aspirated into the lungs. Using a fine hypodermic needle, 11 (eleven) millicure of radioactive kerosene (0.3 cc kerosene) was injected into the stomach.

Following this ingestion the stomach was placed back into normal position and the muscle and skin were sutured. Six hours later the mice were anesthetized, killed and the anterior part of the thoracic wall was removed and each mouse was immersed in isopentane cooled down to -160° F by means of liquid nitrogen. Freezing was instantaneous

The mice were removed from the isopentane and placed in dry ice. Later the desired organs were chipped out with a pick and hammer and stored at 0° C. until needed.

Later, under very low temperature, 4 micron sections were cut using a sliding microtome. These sections were lifted with a camels hair brush into a beaker filled with cold methyl alcohol and stored at 0° C. for one day.

The following day the methyl alcohol suspended sections were allowed to stand in the methyl alcohol at room temperature for one-half hour and then floated onto egg albumin - glycerol smeared slides, allowed to dry in a 37° C. oven overnight. Blood smears were treated in a similar manner. The slides were then dipped in 1% celloidin solution in 100% ethyl alcohol to eliminate artifacts and then into subbing fluid (5% solution of gelatin and 0.05% chrome alum) to effect good emulsion binding.

The slides were then covered with the emulsion from the stripping film and stored in light proof bakelite boxes for sufficient length of time to expose the film adequately to any radioactive material. Following such exposure the slides were developed and examined.

Results

The mixture of kerosene and iso-octane "peaked" at wave length 221 millimicron with a slight peak at 273 millimicron when examined with the Beckman DU Spectrophotometer. The curve obtained from

mixing rat blood with iso-octane 'peaked" at wave length 209 millimicron and steadily declined to wave length 400 millimicron.

The curve, after 1 cc of kerosene was given 18 rats via stomach tube, the rats killed and blood drawn from the inferior vena cava, the blood extracted with iso-octane and this examined with the DU Spectrophotometer - 'peaked" at 221 and 273 millimicrons. The greatest amount of kerosene found in the blood after 1 cc was given via stomach was detected 2 to 4 hours after the administration of the kerosene.

Calculation was made using the formula of H. W. Gerarde.

$$\text{PPM of kerosene} = \frac{\text{mgm aromatic material ml. X volume of sample X } 10^6}{\text{Sample weight (Sp g. of blood X volume)}}$$

The largest amount of kerosene detected in the blood of our rats four hours after placing the kerosene into the stomach was 142 ppm.

Twenty-four hours later, no kerosene was detected in the rats' blood.

When rabbits were used, kerosene was detected in the urine 24 hours after administration of the kerosene via stomach tube. X-rays of the chest of rabbits given kerosene revealed increased densities in those animals in which kerosene was detected in the blood.

Gross and microscopic examination of the tissues revealed areas of consolidation in the lung, degenerative changes in the liver, tubular cells of the kidney and heart. These changes were always found when kerosene was detected in the blood and were not observed in our control animals.

Examination of the radio-autographic slides reveals the presence of the "tagged" kerosene in the following organs and tissues:

1. Stomach
2. Plasma
3. Lungs
4. Liver
5. Kidney
6. Urinary bladder
7. Heart muscle

The spectrophotometric evaluation of the kerosene in the blood of a rat given kerosene via stomach is hereto attached. See page 3.

Conclusions

1. Kerosene can be disseminated rapidly by hematogenous routes from the stomach to many organs and tissues and can be detected in the blood by spectrophotometric methods. Positive chest x-ray findings are found in those rabbits in which kerosene is found in the blood.
2. Significant pathological changes are observed in the lungs, liver, kidney and heart of animals in which kerosene is placed into the stomach and left there.
3. Radioactivity in kerosene administered to mice via stomach tube in minute dosages can subsequently be detected in the blood and various organs by autoradiography.

Acknowledgements

This study was financed in part by the American Petroleum Institutes Medical Advisory Committee through its sub-committee on Specialty Petroleum Products, J. W. Osborn, M. D., Chairman.

The assistance and advice of Colvin H. Agnew, M. D. and L. B. Beentjes, Ph. D., of the Department of Radiology is acknowledged with gratitude.

STANDARD OIL COMPANY
(INDIANA)

910 South Michigan Avenue
Chicago 80, Illinois

October 20, 1959

J. W. OSBORN, M.D.
The Standard Oil Company (Ohio)
Midland Building
Cleveland 15, Ohio

Dear Dr. Osborn:

At your request, I attended the Second Annual meeting of the American Association of Poison Control Centers at the Palmer House in Chicago, on October 6, 1959. Following is a brief summary of what took place. I am also enclosing material that was distributed.

The meeting was fairly well attended and it was reported that there were 121 participating members in the organization at this time. Due to their previous by-laws, a quorum was not present until late in the meeting. By-law changes have taken care of this matter. The dues have been $2.00 per member but due to a change in the by-laws, voted at this meeting, the dues will be $5.00. Many of the members present were pediatricians and pharmacologists. By-law changes were made with which they expect to broaden their membership to other organizations.

In the committee reports, there was a request for educational material for distribution--pamphlets, etc. on poisonous drugs--which could be handled through Health Department contacts. It was recommended that an Education Committee be formed and funds solicited to carry on their activities.

To date, there are 302 poison control centers and it is the desire of the organization to have control centers every 50 miles. Some centers are for information only, while others are for both information and treatment. It was emphasized that adequate training should be given to persons giving out information and recognize the advisability of getting legal advice on matters that may arise as the result of giving out information.

The Research Committee has no funds to date.

A film lending library and a national clearing house for poison control centers is under the Bureau of State Services, Public Health Service, Department of Public Health, Education and Welfare, Washington 25, D.C. They are now getting information from the control centers. Sixty centers report every case treated. At the present time, they have 15,000 poison cases reported on the epidemiological survey and of this 15,000 cases, there are 631 cases of kerosene poisoning. A control of alternating lavage and not-lavage treatment was made on 192 cases. It was reported that 45% of those receiving lavage had complications and 63% of those not lavaged had complications. It was the concensus of opinion at this meeting that lavage was indicated. Dr. R. K. Richards of Northwestern recommended lavage.

Dr. Leslie Corsa stated that it was doubtful that centers were saving many lives but they were permitting an excellent epidemiological survey of poisons and it was also educating both the public and the doctors in regard to poison control.

I feel that it might be worthwhile for the A.P.I. to become a member of this organization in order that they may be in touch with what is taking place and they should be able to add something, pertaining to petroleum products, to the control center.

Yours truly,

/s/ B.B. Reeve, M.D.

Medical Director

BBR:rl
Encl.

REPORT OF SUBCOMMITTEE ON TOXICOLOGICAL REVIEWS

H. W. Gerarde, M. D., Chairman

1. The second editions of the Toxicological Reviews on Butadiene, Naphthenic Acids, Copper Naphthenate, and Naphthalene have been published.

2. Final drafts have been prepared on Benzene, Toluene, and Xylene. Publication is expected in early 1960.

3. A large number of first drafts of Toxicological Reviews have been received from Dr. Phillip Drinker.

4. It is anticipated that $5,000 will be needed for revision of the Toxicological Reviews during the coming year.

5. The first drafts of the Toxicological Reviews will be circulated in groups of four to the members of the Medical Advisory Committee for comments and suggestions.

Respectfully submitted,

H. W. Gerarde, M. D., Chairman
Subcommittee on Toxicological
Reviews

APPENDIX L-1

REPORT OF SUBCOMMITTEE ON INDUSTRIAL HYGIENE

J. A. Spence, Chairman

This subcommittee met on November 7, 1959 with 10 members and 15 guests present. Mr. E. P. Wheeler was absent.

Liaison members reported on the activities of the American Standards Committee Z-37 Toxic Dusts and Gases, Z-4 Industrial Sanitation, and Z-62 Industrial Hygiene Standards. Mr. Dooley reported work is in progress revising certain standards. Mr. Hendricks reported the first draft of Guide To Good Industrial Hygiene Practices will be presented at the April 1960 meeting of the Z-62 Committee.

Work on the petroleum catalyst project has been completed. The subcommittee submits to the Medical Advisory Committee the report "Some Catalysts Used in Petroleum Refining" with the recommendation it be used for distribution within API only.

The subcommittee has begun the preparation of industrial hygiene information on various petroleum refining processes. Initial attention will be given to the following processes: 1) reforming, 2) cracking, 3) alkylation, and 4) isomerization. Members have accepted the following assignments.

Alkylation - Mr. Spence
Cracking - Messrs. Daniels, Pabst, and Wilkening
Isomerization - Messrs. Dooley and Renes
Reforming - Messrs. Halley and Hendricks
Mr. Wilkening will be project leader.

Deadline for completion of the first draft is March 1, 1960. Following completion of this first phase, attention will be given to 1) polymerization, 2) solvent refining, 3) treating, and 4) selected refining processes.

Present work by the C_9 - C_{12} subcommittee indicates these aromatics may be more toxic than previously considered. There is therefore a need to evaluate the industrial hygiene aspects associated with these aromatics. Since there is an apparent lack of information, the subcommittee members have agreed to gather data on their uses and related environmental health conditions. It is anticipated that by the November 1960 meeting additional information on the industrial hygiene problems will be available to supplement the final findings of the C_9 - C_{12} subcommittee.

J. A. Spence, Chairman
Subcommittee on Industrial Hygiene

SUBCOMMITTEE ON ATMOSPHERIC POLLUTANTS
LIAISON REPORT TO SMOKE AND FUMES COMMITTEE

The Subcommittee of the Medical Advisory Committee of API which concerns itself with atmospheric pollutants brings greeting to you gentlemen here through me as its liaison.

You gentlemen are well aware that the Petroleum Industry has been accused of being responsible for certain pollutants found in the air and that these pollutants have been alleged to arise from the manufacture, refining, production, storage, transportation, sale and use of petroleum and petroleum products. When you have discussed and analyzed these air pollutants, you find they make a considerable list which includes - SO_2 and its variants, O_3, CO and oxidents such as hydrocarbons, NO_2 with its olefins, etc.

Because the public, or people, have at times complained of eye irritation, decreased visibility, coughing, etc., all of the pollutants I have mentioned have been accused of injuring our health. It was presumed and supposed that air pollution was a menace to public health and that anyone coming in contact with polluted air, as we have it in our urban areas, would become a cancer victim, might die of tuberculosis, would acquire a continuous bronchitis, would lose their eyesight or finally might suffocate to death.

Our newspaper and feature writers and the people themselves blamed our industry for causing this terrific nuisance, this nuisance that might kill, this nuisance that has been caused by a large, prosperous industry, worldwide in its operations, and which is accepted in the lives of each one of us for our comfort and existence. We, as people, are very anxious to abate air pollution and particularly if we find we are responsible for it. As we learn the answers we have attempted to meet the problems. If there are still problems, we may still find answers as we are still working at it.

In the past years, the petroleum industry has spent many millions of dollars and, to quote Mr. McAfee, during years 1956, 1957 and 1958 approximately 66 million dollars was spent to abate this nuisance. These abatement efforts have been good because there has been a control on our stack effluents, there have been changes in our refinery methods, there has been a redesigning of storage tanks and tank trucks and terminal distribution stations and many other worthwhile changes. In addition, huge sums of money have become available for our use in technical researches which we hope will solve, eventually, the problem of air pollution. Much of this technical money is available on the assumption that air pollution is a menace to the health of mankind. Those in favor of this assumption always argue that the Donora, Meuse Valley and London incidents are examples of medical hazards.

Communication has been bad, especially through newspapers and other articles published by individuals in scientific magazines. These articles concerning "smog" often stress unproved facts and many of them are deleterious to the Petroleum Industry. Politicians have become very vocal, especially when running for office in localities where air pollutants are more obnoxious than in other parts of the country. It is now rapidly becoming evident that the weather, the population density, geographical locations, seasonal changes, industry and the number and type of automobiles on the highways are certainly not subject to laws or county ordinances. The opinion of people and particularly the fringe of armchair scientists who are always vocal, will be a deciding factor in the elimination or abatement of air pollution because in their demands they will push researchers and others to extreme activity in eliminating this nuisance.

In spite of the claim that air pollution, or "smog", affects the health of

the individual, both physically and mentally, we have found no case, nor have we found any pathological effects, attributable to atmospheric pollutants. There are many poisonous and noxious fumes which only become noxious when they exceed a certain density and are either respired or ingested - not once but continuously over a period of time. The human being may withstand the effects of a relatively large dose of a substance for a short time without any harmful effect but cannot withstand the same substance in smaller doses for a long period of time. It therefore seems necessary that certain standards be developed that are scientific and not based on assumption or fear concerning concentrations of pollutants which the human being may contact without harmful effect. This is complicated by age and state of health of the individual and indirectly by his activity or inactivity. Hence, in establishing standards we must establish standards at an extremely low level so that the pollutants will not harm the most susceptible individual, whether it be one with an allergy or one who has a disease such as bronchitis, tuberculosis, heart disease, etc. We must establish these standards not because we think it will harm the human being, but because we think it might harm him.

To date in our urban communities, the U. S. Public Health Service has been unable to prove aggravation of such diseases as asthma, tuberculosis, bronchitis, etc., due to air pollution, nor does air pollution particularly affect the aged or the very young. Four precepts are necessary to establish any casual relationship between air pollutants and health - namely:

1. A toxic effect has occurred.
2. A pollutant capable of causing this effect is (or has been) present.
3. There is (or has been) an excessive exposure to the pollutant.
4. Other causes of the toxic effect do not exist.

By toxic effect is meant real injuries that are self-evident or readily demonstrable by appropriate medical examination.

Your attention is called to the difference between a nuisance and a hazard. When does an annoyance or a nuisance become a medical hazard? If a thing interferes with the comfort or the enjoyment of a man's property, or it renders life uncomfortable, it should be considered a nuisance. It may be a nuisance in one place but not in another. If a number of people are affected it is a public nuisance, otherwise with one person it becomes a private nuisance. When we have an obnoxious odor it is an aesthetic nuisance and may cause damage by reducing the price of real estate, but it certainly is not a medical hazard because it has not made anyone sick. It could be a medical nuisance because it makes you sneeze or it might annoy you because your eyes smart, but it does not hurt them. There has been no case of any permanent damage to anybody's eyesight because of air pollutants.

It is sincerely hoped that this Committee will differentiate, in its research and in its reporting and evaluation of constituents of air pollution, between medical hazard and nuisance and not presume that all are medical hazards.

As true Americans we do not like to have our rights infringed upon, whether it is the inability to see as far as we desire or whether it is the discomfort and eye smarting that occurs at times with air pollution. We just don't like it and we in the Petroleum Industry, who are people, will do everything in our power to assist in the abatement of air pollution.

Gentlemen, this talk I have just given to you is a condensed version of a talk I recently gave to a combined two-day meeting of my Subcommittee and members of the Automobile Manufacturers Association, the American Association of Railroads

and technical and medical representatives of the U. S. Public Health Service at the Robert A. Taft Sanitary Engineering Center in Cincinnati. The API, through its Subcommittee on Atmospheric Pollutants, hosted this meeting which was the first of its kind to be held. Representatives of your Committee who were present and who participated in the program were Mr. W. T. Gunn and Mr. Jerry McAfee.

In addition to this, the Medical Advisory Committee has received to date two parts of Dr. M. W. Goldblatt's final report. His contract with the API concerning Project MC-4 terminated on July 1, 1959 and he informs us we can expect three more portions of this report before it is concluded. The Medical Advisory Committee is requesting that this report be printed, multilithed or reproduced in book form for distribution to members of your Committee, the various oil companies within the Institute and others interested in this research. This report is one of the best works ever to be done concerning a critical, clinical analysis and review of the world's literature todate, especially that literature which concerns air pollutants which might be caused by the manufacture, refining, production, storage, transportation, sale and use of petroleum and petroleum products.

Respectfully submitted,

John C. Ruddock, M. D., Chairman
Subcommittee on Atmospheric Pollutants,
Medical Advisory Committee,
American Petroleum Institute

REPORT OF LIAISON MEMBER TO THE A.M.A. COMMITTEE ON TOXICOLOGY AND THE INTER-INDUSTRY GROUP ON LABELING

1. Status of Hazardous Substances Labeling Legislation

A. Federal Level - The first session of the 86th Congress adjourned in September without taking any action on S.1283 and H.R.5260 (identical bills sponsored by the Inter-Industry Group "to regulate the interstate distribution and sale of packages of hazardous substances intended or suitable for household use"). The Senate Committee on Interstate and Foreign Commerce held one hearing August 13 at which time the API was represented by M. D. Gjerde and J. W. Osborn, M. D. Dr. Osborn read a prepared statement on behalf of the API supporting the position of the Inter-Industry Group. No hearings were held on H.R.4260. Likewise, no hearings were held on H.R.7352, a bill sponsored by the American Medical Association "to regulate the labeling of hazardous substances for non-manufacturing purposes." Dr. Osborn is in touch with Mr. Gjerde, Chairman of the API Interdivisional Committee on Labeling, and with Mr. Ackerly, counsel for the C.S.M.A. Labeling Committee, on current developments. It is expected that further action will occur soon after Congress convenes its second session in January, 1960.

B. State Level -

1. Ohio -- Amended Substitute Senate Bill No. 440 was enacted by the Ohio General Assembly to become effective November 4, 1959. As of October 20, the Ohio Department of Health had not promulgated any regulations for the administeration of the labeling law. Also, department officials indicated that the General Assembly did not appropriate any money for hiring of additional personnel necessary to properly enforce the law. These officials said that because of the lack of an appropriation, they would move rather slowly in promulgating regulations and adopting enforcement procedures but emphasized that they would expect the law to be complied with. The above information is the gist of that supplied by Mr. Addison E. Dewey, Director of the Ohio Petroleum Council in Columbus in his information bulletin dated October 20, 1959. A printed copy of the Ohio law was sent to Mr. E. O. Mattocks on October 22 for duplication and distribution to interested API members.

2. Illinois Senate Bill No. 911 -- As of June 11, 1959 this bill covering household products and almost identical to the model law which the API Labeling Committee helped to develop had just been adopted. This Act is supposed to take effect January 1, 1960 but no further information has been received regarding issuance of rules and regulations by the Director of Health.

3. Indiana -- Amended Senate Bill No. 103 was passed March 1959 and is expected to take effect January 1, 1960. Likewise, no rules or regulations for its enforcement have been made available to this member to date.

4. City of New York -- Revision of the Sanitary Code, Title IV; Environmental Sanitation, Article 211: Hazardous Substances. Presumably, this new law announced last February as being passed went into effect in New York City on or about October 1, 1959. No further information on any rules or regulations or enforcement procedures has been received by this member to date.

5. Vermont H. 283 -- This bill introduced March 13, 1959 was essentially the same as the Inter-Industry Group draft of January 5, 1959. Subsequently, on April 1, 1959 Vermont H.B.460 was introduced. This bill did empower the Department of Health to regulate the labeling of food, drugs, cosmetics, and all hazardous substances. The legal section of the Committee on Public Affairs of the API indicated that the sections of this bill dealing with hazardous substances followed closely the model bill sponsored by the Inter-Industry Group. No word has been

received on the subsequent fate of either of these bills.

6. Washington - H.B. No. 437 passed the House with minor amendments but was killed by a Senate Committee on March 5. The State Legislature adjourned on March 12 with no opportunity to revise the bill at that session.

There may be bills before other State assemblies during 1959 but this member has no information on other than the above.

J. W. Osborn, M. D.
Vice Chairman,
Medical Advisory Committee

APPENDIX O-1

REPORT ON ACTIVITIES OF THE API INTERDIVISIONAL COMMITTEE ON LABELING

During the past year the API Interdivisional Committee on Labeling has continued its work to determine requirements for precautionary labeling of petroleum products. In accordance with the policy established by API, we have also followed the general situation with respect to pending or anticipated legislation which may be of concern in this connection.

At their meeting yesterday, the committee approved label wording for Ethylene Glycol Anti-Freeze, Methanol Anti-Freeze, Aromatic Petroleum Oils (with fraction boiling over 700°F.), Cut-Back Petroleum Asphalts (flash 20°F. - 80°F.), and Cut-Back Petroleum Asphalts (flash 80°F. - 120°F.).

The above will be included in a new issue of API Bulletin (2511) on Precautionary Labels, bringing the total to 21 product labels.

Liaison has been maintained with trade organizations having interest similar to ours with respect to labeling legislation. It is the committee's intention to continue this effort to encourage proper labeling requirements promulgated at both State and Federal levels.

Mr. Gjerde will communicate with the MAC on request of the committee for early revision of toxicological reviews on kerosine, aromatic naphtha, methyl alcohol, and others, if needed.

Prepared by M. D. Gjerde and Dr. C. H. Hine.

APPENDIX P-1

WAX RESEARCH ADVISORY COMMITTEE

The wax research project, under the direction of Dr. P. Shubik of the Chicago Medical School, is proceeding most satisfactorily. To date, no known carcinogen had been found in any of the waxes examined. The limit of sensitivity of the test is 0.01 p.p.m. Of the five waxes subjected to extensive biological testing (mouse skin painting, rabbit skin painting, injection into mice, and feeding at a 10% level in the diet of rats), none have shown any significant biological results. Some of these tests have now been in progress over 65 weeks.

In the spring of 1959, unfavorable publicity, attributed to a National Cancer Institute specialist, appeared in a great number of newspapers throughout the United States. Through the efforts of Dr. Shubik and many of the members of the Wax Research Advisory Committee, the immediate crisis was met. Ultimately, on June 29, 1959, representatives of the Committee and Dr. Shubik met with Secretary Flemming of the Department of Health, Education, and Welfare, Surgeon General Burney of the U. S. Public Health Service, Commissioner Larrick of the Food and Drug Administration, and Dr. Major, Associate Director of the National Cancer Institute. The results of this meeting was the attached statement by Secretary Flemming at his news conference on June 30, 1959.

As a result of the work sponsored by the Wax Research Advisory Committee, Mr. Frank Porter has written to Secretary Flemming requesting an extension of time for wax for one year beyond March 6, 1960, the date on which, under Public Law 85-929, a decision on the suitability of wax as a food container coating would otherwise have had to be rendered. Mr. Porter has received the attached reply from Mr. Larrick, Commissioner of the Food and Drug Administration.

The Wax Research Advisory Committee believes it essential that the work at Chicago Medical School be continued for another year, at a budgetary level of $150,000.

There is urgent need to acquaint the public with the advantages of petroleum wax for use in food packages. This is especially needed at this time with petroleum wax competitors undermining the public confidence in petroleum wax. The Wax Research Advisory Committee plans to request the Medical and Health Committee to recommend to the API Board of Directors that they instruct their Committee on Public Affairs to undertake this task immediately and to form a Wax Advisory Committee to assist them in their program.

The Committee would like to commend Mr. E. O. Mattocks for his invaluable guidance and assistance throughout the year.

Respectfully submitted in behalf of the
Wax Research Advisory Committee
by

R. E. ECKARDT, M. D., Chairman

REE:Mew
Attach.: Statement by Secretary Flemming, June 30, 1959.

FOR RELEASE AT CONCLUSION
OF NEWS CONFERENCE

Statement*
by
Arthur S. Flemming
Secretary of Health, Education, and Welfare

I am informed that both the Food and Drug Administration and the Public Health Service are receiving many inquiries about possible cancer producing agents in wax used for milk cartons and other food containers.

I think we should try to clarify the situation with respect to these waxes.

During the latter part of 1956, Dr. W. C. Hueper, of the Public Health Service, arranged with the Milk Industry Foundation to collect waxes used by dairies for the impregnation of milk containers. Several months later the Foundation assembled about 40 waxes for further chemical and biological analysis and sent them to the National Cancer Institute. In June 1957, 24 of these waxes were sent for study to Dr. Philippe Shubik, Division of Chemistry, Chicago Medical School. Dr. Hueper provided Dr. Shubik with suggestions for the work and data on the economic, chemical, and biological aspects of dairy waxes. A representative sample of each of these waxes was retained by the National Cancer Institute's Environmental Cancer Section of which Dr. Hueper is chief.

In the fall of 1957, Dr. Hueper received a report from Dr. Shubik on results of preliminary tests of the 24 waxes. The studies were performed by Dr. William Lijinsky, an associate of Dr. Shubik's. It was demonstrated in these studies that one of the waxes contained a known carcinogen (cancer producing agent), 1,2,5,6,-dibenzanthracene. Three additional waxes were suspected but no carcinogen could be identified. It should be noted that while this compound has produced cancer in laboratory animals, 1,2,5,6,-dibenzanthracene has not been shown to produce cancer in man.

A report of the results of this investigation was communicated to Mr. Ernest Kellogg, Secretary of the Milk Industry Foundation. As a result, Mr. Kellogg asked the American Petroleum Institute for assistance in investigating the problem.

Dairy industry representatives also met with Public Health Service milk and food personnel to map out a program to assure that the waxes used were free from impurities. In November, 1957, the American Petroleum Institute made available $100,000 a year for five years to support additional studies by Dr. Shubik (Dr. Shubik has indicated that the results will be published as the studies are completed.)

Accordingly, Dr. Shubik was supplied an additional sample of 26 representative waxes by the petroleum industry. By the time these new samples were received, Dr. Shubik had improved his analytical techniques to the point where he could identify as little as one part of 1,2,5,6,-dibenzanthracene in one-half billion parts of wax. In the earlier experiments, sensitivity was one part of 1,2,5,6,-dibenzanthracene in one million parts of wax. With the high sensitivity of the new techniques, no dibenzanthracene has been found in any of the 26 samples.

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*Released at News Conference, Washington, D. C., June 30, 1959.

Meanwhile, in 1958, samples of the 24 waxes sent to Dr. Shubik by Dr. Hueper in 1957 also were sent to Dr. Paul Kotin, Associate Professor of Pathology at the University of Southern California. The major results of this study, made by Falk, Kotin and Miller, were published in the April 25, 1959, issue of a British scientific journal, Nature (pp. 1184-85).

The Kotin investigations confirmed the Shubik findings that one wax contained between 0.5 and 1.0 micrograms per gram of 1,2,5,6,-dibenzanthracene. The Kotin investigations demonstrated, in addition, that 1,2,5,6,-dibenzanthracene added to dairy waxes for experimental purposes was extracted from thin layers of wax by milk.

The results of these studies have been reviewed by scientists of both the Public Health Service and the Food and Drug Administration. I am advised that the findings are not final but no indications of a health hazard have been found. The Food and Drug Administration advises there is at present no basis for action concerning these waxes under the Food, Drug, and Cosmetic Act.

The scientists are also agreed that more information is needed. The Food and Drug Administration plans a study of these waxes in its own laboratories if its appropriation for 1960 as now approved by both House and Senate is finally enacted. The Public Health Service also plans to support further studies and to provide technical assistance to the industry in its control program.

It should be pointed out that the new food additives amendment to the Federal Food, Drug, and Cosmetic Act covers the safety of food container materials which incidentally contaminate food, just as it covers additives for direct addition to food.

AMERICAN PETROLEUM INSTITUTE

50 WEST 50TH STREET
NEW YORK 20, N. Y.

FRANK M. PORTER, PRESIDENT

October 15, 1959

Subject: Extension for Waxes

Mr. Arthur S. Flemming, Secretary
Department of Health, Education, and Welfare
Washington 25, D. C.

Dear Mr. Flemming:

Since February 1, 1958 the producers of petroleum waxes have financed an investigation which has been sponsored by the API to determine the toxicity of petroleum waxes. This investigation has been under the direction of Philippe Shubik, M. D., at the Chicago Medical School.

While considerable information has been obtained to date on the various types of waxes produced by the petroleum industry, insufficient time has been available to complete these tests, especially the biological tests on animals. It is expected that at least another year, and possibly two, will be needed before conclusive evidence is available which could be included in a petition to be filed with the Food and Drug Administration in accordance with the Food Additives Amendment to the Food, Drug, and Cosmetic Act. If the producers of petroleum wax were required to file a petition prior to March 6, 1960, in accordance with the Food Additives Amendment, insufficient data would be available to adequately judge the potential toxicity of these materials which are used in food packaging.

You will recall that on June 29, 1959, you and some of your staff were brought up to date on the status of the API wax investigation. Since that time some of the Food and Drug Administration people have been kept informed of the current developments in the wax investigation.

On behalf of the petroleum wax producers, the American Petroleum Institute would like to ask for an extension of time of not less than one year before they have to comply with the requirements of the Food Additives Amendment. At the end of this period of time, we will be in a position to know whether a formal petition can be submitted in accordance with the Food Additives Amendment or whether we will wish additional time to properly conclude the investigation.

Very truly yours,

Frank M. Porter

FMP:ed

cc: R. H. Ahlborth, M. D.
E. O. Mattocks

Copy From E. O. Mattocks For Information Of Members Of: Advisory Committee to the Wax Research Project and Observers; Interdivisional Committee on Petroleum Food Additives 10/15/59

OIL'S FIRST CENTURY
BORN IN FREEDOM
WORKING FOR PROGRESS

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON 25, D.C.

October 27, 1959

Mr. Frank M. Porter
American Petroleum Institute
50 West 50th Street
New York 20, New York

Dear Mr. Porter:

Secretary Flemming has asked that we reply to your letter of October 15, 1959, in which you requested an extension of time under the Food Additives Amendment, permitting the continued use of petroleum waxes pending completion of the current research program.

The Food and Drug Administration has not, as yet, granted extensions as authorized by the Food Additives Amendment. We have adopted the policy that such extensions will be granted where there is a showing that the material to be covered by an exemption has been used without apparent injury to consumers and data is available demonstrating that continued use would be without hazard to the public health and that the extensions are necessary. We recognize that the studies on petroleum waxes are in progress, were started seasonably, and further, that they cannot be completed prior to March 5, 1960. Thus, we may be in a position to grant an extension in this instance of up to one year, which, incidentally, is the maximum period of time which we can grant under the existing law. We have no statutory authorization for granting extensions beyond March 5, 1961.

Before we can take final action in this matter, we will need more precise information as to the identity of the petroleum waxes you would propose be covered by such extension and the food uses to which they will be put. We would also need for the record a summary of the work completed indicating that the waxes to be covered by the extension may be safe and a status report on the investigations still in progress. It may be that it would be advisable first to have these scientific matters discussed at a conference between the scientists of the Food and Drug Administration and those engaged in the study. We would suggest that this be arranged for early January, which will permit an additional two month's experience with the studies currently in progress.

As indicated above, if the data which you furnish us in January indicates that continued use of the petroleum waxes does not present a hazard to the public health, we will be agreeable to an extension for whatever additional time is necessary, up to March 5, 1961.

Sincerely yours,

Geo P. Larrick

George P. Larrick
Commissioner of Food and Drugs

API MAC QUARANTINE SERVICE

Miss Regina Burns informed us by telephone today that their branch of the Public Health Service is being reorganized as of the first of the year. Dr. Ralph W. McComas will be Chief of the Epidemiology and Domestic Operations Branch. In the meantime, Miss Burns will continue to act as liaison with us in the field of quarantine.

G. M. Saunders, M. D.

APPENDIX R-1

INDUSTRIAL HYGIENE BULLETIN

STANDARD OIL COMPANY OF CALIFORNIA

1958 FOOD ADDITIVE AMENDMENT
Typical Information Which May be Needed for Petitioning FDA

The most significant feature of the 1958 Food Additive Amendment to the Federal Food, Drug and Cosmetic Act is that it places the responsibility on the user and manufacturer to show affirmatively that the product to be used is safe and presents no hazard to its consumer. The law requires that the user now file a petition for use of his food additive under conditions of intended use. If he can prove it is safe, the FDA will approve its intended use.

"The term 'Food Additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food."

To assist those who wish to seek clearance of Company products under the Food Additive Amendment, the following information should be included in the petition:

A. Food additive identification and composition
B. Food additive use
C. Physical and technical effects establishing the food additive as affecting the food
D. Methodology
E. Safety of the food additive

INFORMATION REQUIRED FOR PETITIONING FDA

A. FOOD ADDITIVE IDENTIFICATION

1. Name of Product

   a) common name

   b) other names, including trade name

   c) chemical name following the nomenclature accepted by Chemical Abstracts

2. Formula

   a) Empirical formula

   b) Structural formula

   c) Molecular weight

3. Definition of food additive

A. Components	% Wt.	Brief description of manufacturing process

B. Include equations for chemical reactions involved

4. Description of product: liquid, solid, crystalline, amorphous, color, odor, taste, stability

5. Physical, chemical and/or biological properties

Solubility

Cold water

Hot water

Alcohol & acids, etc.

Melting point

Boiling point

Specific gravity

Refractive index

Viscosity

Optical rotation

Ph

Ash

H_2O content

Iodine number

Saponification number

Alkoxyl content

Volatile matter

Water-insoluble matter

Other extractables

Biological activity

Absorption spectra in ultraviolet and infrared

Fluorescence spectra

Readily carbonizable substs.

Readily oxidizable substs.

Stability, etc.

6. Purity. Specification prescribing the minimum content of desired components.

7. Impurities. Specifications limiting arsenic and lead and also other known undesirable reaction byproducts or impurities. Details of suitable tests for checking the specifications.

(Where such information is not available, a statement as to why it is not should be submitted)

8. Identification tests

9. Assay procedure

10. Other pertinent data

3. FOOD ADDITIVE USE

1. The amount of the food additive proposed for use

2. Purpose for which it is proposed

a. Directions, recommendations and suggestions regarding the proposed use

b. Include sample of proposed label for the food additive

3. "If the additive results or may expect to result from the use of packaging material, the petitioner shall show how this may occur and what residuals may reasonably be anticipated."

a. Determine quantity of each residue on various foods and identify residue.

(1) Calculated maximum contaminations, include sample calculations

(2) Solvent extraction using 5 solvents at 135°F for one week (water, 20% sucrose, 1% citric acid, 3% acetic acid, 3% sodium chloride, edible oil or lard) - with solubility curves if indicated.

(3) Quantity and transfer data and description of method used.

4. Suggested tolerance limitation on food

C. PHYSICAL AND TECHNICAL EFFECTS ESTABLISHING THE FOOD ADDITIVE AS AFFECTING THE FOOD

1. Is the additive stable or unstable

2. Will it be expected to become a component.
If yes, how much? What products are formed?

3. Will it affect the characteristics of the food directly or indirectly?
If yes, how?

Note: These data should include information in sufficient detail to permit evaluation with control data.

4. What is the smallest quantity of the additive necessary to produce effect expected? Data from carefully controlled experiments showing the degree of effect accomplished by the additive at several different levels of concentration in food must be obtained. The number of levels of concentration will depend upon a number of factors such as the toxicity of the additive, the particular foods involved, the proposed usage level and the increment of the additive required to induce any noticeable change in the food.

D. METHODOLOGY

1. "A description of practical analytical methods to determine the amount of food additive in raw, processed and/or finished food or any substance formed in or on such food because of its use."

"In order to demonstrate that the analytical method is sufficiently reliable and specific, validation data should be submitted. These data will consist of food 'blanks' (values obtained by the method on food containing no additive and expressed as 'apparent' additive) and recoveries of the additives added to such food at approximately the tolerance level, both in the presence and in the absence of other chemicals expected to be in the food. Further, the validation data must demonstrate that the method is applicable to each food in which the additive is to be used. The method should generally be accurate to within at least ± 10% at the tolerance level and be sensitive to about 10% of the tolerance level. The blank on a food containing no additive should be reasonably reproducible and should not exceed 10% of the tolerance."

"The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel."

E. INVESTIGATION MADE ON THE SAFETY OF THE FOOD ADDITIVES

1. Results of animal tolerances (detailed results and description of methods)

a) Acute oral LD_{50} Rats

b) Acute dermal LD_{50} Rabbits

c) 30 or 90 Day Subacute Feeding Rats

d) 2-year Feeding Rats

e) 2-Year Feeding Dogs

2. Reports of investigation that would bias a "safe" evaluation of the food additive.

3. Check for presence of known carcinogens, if expected.

f. PROPOSED TOLERANCES FOR THE FOOD ADDITIVE FOR SPECIFIC USES
(A petitioner may include a proposed regulation)