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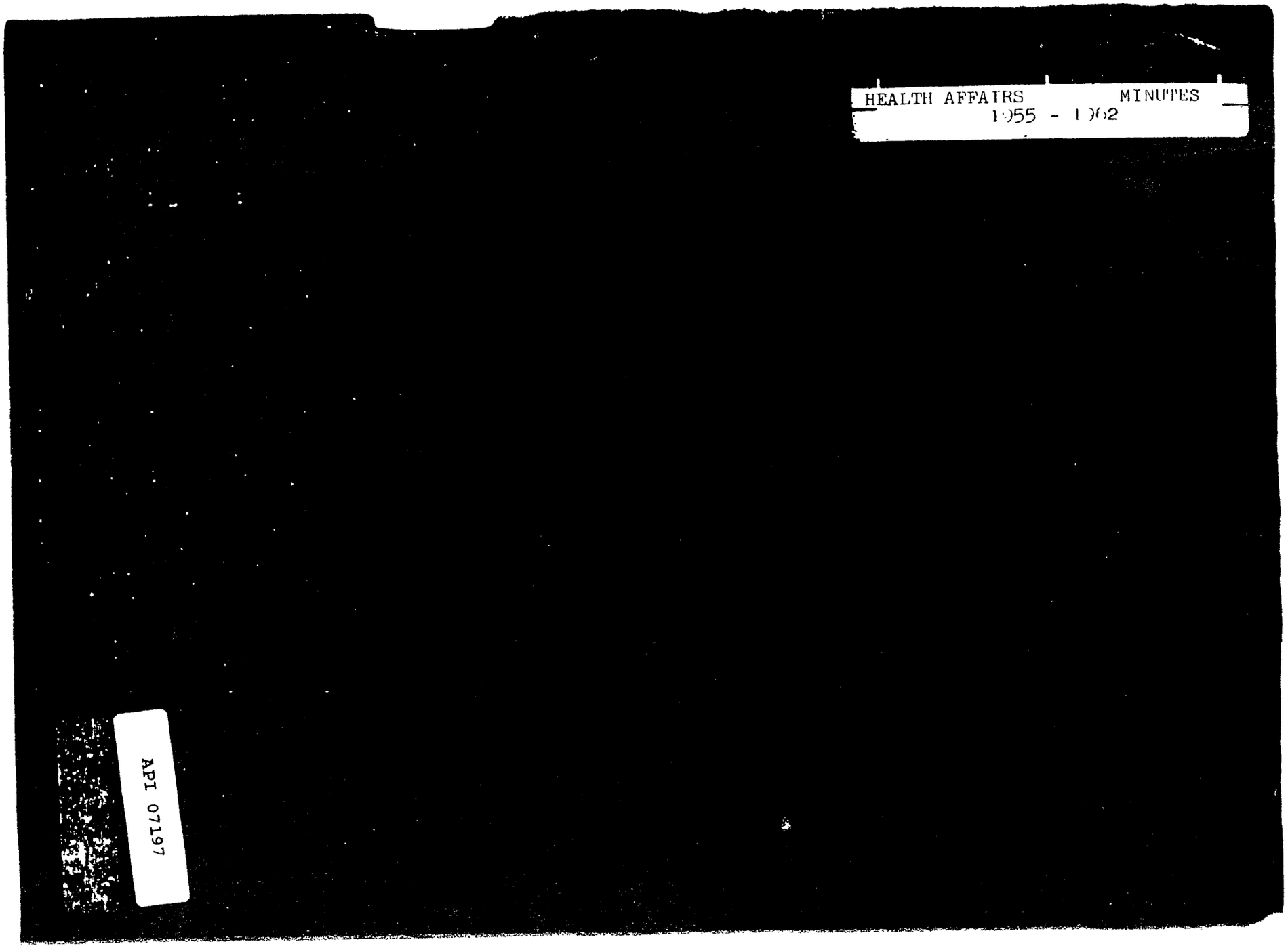
HEALTH AFFAIRS MINUTES
1955 - 1962
API 07197

Wax
Rept.
by
Eckardt

APPENDIX D
To Minutes of 22nd MAC Meeting

Report of the Subcommittee on Carcinogenicity

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

PART 1 - API RESEARCH PROJECT MC-1

In respect to the Subcommittee's report on the research activities at the Kettering Laboratories, there is little additional to report beyond that was reported by the Subcommittee in April. Budget proposals were submitted at that time and need no revision other than that the Subcommittee does not believe it will need $15,000 for epidemiological studies in 1957-1958. The Subcommittee submits without comment an interim report* from the Kettering Laboratory dated November 1, 1956.

PART 2 - TOXICOLOGY of PETROLEUM WAX

Recent newspaper publicity concerning the carcinogenicity of waxes which may be used on milk cartons, have lead the Subcommittee on Carcinogenicity to consider it advisable to conduct biological testing which will help evaluate the carcinogenicity of waxes. In addition, it is the belief of the Subcommittee on Carcinogenicity that waxes, other than milk carton waxes which might also be used in the food industry, should also be included in this testing program in order to develop a more complete picture of the situation concerning waxes. In view of this, the subcommittee recommends the following courses of action to the Medical Advisory Committee:

1) A survey of the types of waxes which are used in the food industry should be undertaken in order that a complete understanding of the types of waxes which come in contact with food can be had by the subcommittee.

2) Following the above survey a selection of samples from these waxes should be made in order to provide a potential range of carcinogenic activity in the waxes sampled, which will be determined by the following factors:

    a) The crude source.
    b) The oil content.
    c) The degree and type of refining.

*Note - Copies of the Interim Report were distributed to those in attendance at the 22nd MAC Meeting. Copies are available to other members of the Medical Advisory Committee upon request to D. V. Stroop. 11-30-56

Rough Draft #1
September 13, 1956
R. E. Eckardt, M. D./cjh

Leroy E. Burney, M. D.
Surgeon-General
U. S. Public Health Service
U. S. Department of Health,
Education, and Welfare
Washington, D. C.

Dear Dr. Burney:

API complains to Surgeon General abt. Hueper's reported talk in Rome — News publicity on milk wax 8/56

On Tuesday, August 21, 1956, a news report of a symposium of The International Union Against Cancer, held in Rome on August 10-15, 1956, appeared in THE NEW YORK TIMES, under the by-line of Arnaldo Cortesi, which said, in part, the following:

> "The report said certain mineral oils and paraffins used for coating milk cartons had produced cancer in man and experimental animals."

Subsequently, in TIME MAGAZINE of August 27, 1956, there appeared the following:

> "Among suspects (as cancer causing agents) certain paraffins used for coating milk cartons."

As anticipated, these two news articles have precipitated a multitude of inquiries to our industry from container manufacturers, dairies, and even milk consumers. In essence, these inquiries have concerned themselves with the validity of these news releases.

In our attempt to develop the facts in this situation, Dr. Hueper has kindly provided a copy of the manuscript which he delivered at Rome, which was referred to in THE NEW YORK TIMES article, as well as a copy of the Report of the Symposium at Rome. After careful perusal of both of these documents, the only reference we could find which could have been misinterpreted by the news reporters is contained on page 22 of the Report of the Symposium and reads as follows:

> "4. Since various petroleum constituents including certain mineral oils and paraffin, have produced cancer in man and experimental animals, the presence of such chemicals in foods appears to be objectionable, particularly when such materials are subjected to too high temperatures."

You will note that no specific reference is made to milk carton coatings.

The petroleum industry has been aware of its responsibilities to its own employees, its customers, and the general public, in the field of carcinogenesis. In this respect, it has had a Subcommittee on Carcinogenicity of its Medical Advisory Committee for over 10 years. During the past 8 years, the Subcommittee

EXHIBIT E
TO MINUTES OF 23RD MAC MEETING

Report of the Subcommittee on Industrial Hygiene
Paul D. Halley, Chairman

I. American Standards Association Committees

A. ASA-Z37 Committee on Maximum Acceptable Concentrations of Toxic Dusts and Gases:

Mr. A. E. Dooley, API Representative to the Z-37 Committee reported on their activities. A standard for formaldehyde has been submitted to the ASA for approval. A standard on carbon tetrachloride has already been approved and is ready for sale.

A summary of tentative standards being considered by Committee ASA-Z37 with information considered pertinent has been prepared by Mr. Dooley. Copies of this summary will be made available to the MAC Subcommittee on Toxicological Reviews.

B. ASA-Z4 Committee on Industrial Sanitation.

Mr. Dooley reports that this committee which is concerned with the promulgation of standards for industrial sanitation has not been active the past 6 months.

II. The main business of the Subcommittee was to review a monograph titled "Health and Physiological Safety in the Process Industries" prepared by the M. W. Kellogg Co. This manual had been obtained by Dr. Curtis and was circulated to the members of the Subcommittee in order to obtain their thoughts concerning its value to the API.

The Subcommittee recognized numerous technical inaccuracies in the manual and recommends that it should not be distributed in its present form. However, the Subcommittee wishes to compliment the M. W. Kellogg Co. for initiating a project of this magnitude.

In considering the merits that a revised text of Kellogg would have to the oil industry, Subcommittee members were of the opinion that such a publication would have some value, but that at the present time, the Subcommittee is not in a position to undertake a project of such volume and scope.

Accordingly, the Subcommittee voted to defer for one year, a decision on the preparation of such a manual.

EXHIBIT G
To Minutes of 23rd MAC Meeting

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

The Subcommittee on Carcinogenicity has held several meetings since the last meeting of the Medical Advisory Committee. Basically it has been concerned with two problems during this interval.

The first of these problems concerns the potential carcinogenicity of waxes used on milk cartons, and was precipitated by a meeting of the Cancer Prevention Committee of the International Union Against Cancer, held in Rome in August 1956. At that time, it was proposed in newspaper releases of the Cancer Prevention Committee that milk carton wax was suspect as a carcinogen. Although it is the opinion of the Subcommittee that milk carton wax presents no hazard to the consuming public, the same cannot be said about other waxes which may come in contact with food. Nonetheless, it is believed that the newspaper reports of the meeting in Rome cannot be ignored and that the petroleum industry should prepare itself to show conclusively that milk carton and other waxes do not present a hazard to the consuming public. It is the belief of the Subcommittee, as a result of the review of the literature, that the petroleum industry today is not in a position to make an adequate defense of this position. In view of this, therefore, the Subcommittee recommends, as already recommended to the MAC at its November meeting, the following courses of action:

milk carton wax studies needed

1. A survey of wax uses which will bring wax into contact with foods or into use as food packages should be reviewed.

2. Biological tests of selected waxes from the above uses should be undertaken in accordance with the outline of carcinogenic testing submitted to the Subcommittee by one of the three following laboratories:

    a. Dr. Philippe Shubik's laboratories at the Chicago Medical School.

    b. Dr. Lloyd Hazleton's laboratories under the direction of Dr. Ivor Cornman.

    c. Dr. Norton Nelson's laboratories at the Institute of Industrial Medicine.

    The specific proposals of these three laboratories are available in the files of the Subcommittee and can be made available to any group which has a valid interest in them. The Subcommittee recommends the above three laboratories in the order indicated, although it suggests that any of the three laboratories would be in a position to conduct competent studies on this problem.

C. Smoke and Fumes Committee

J. C. Ruddock, M. D., reported that the liaison with the Division of Refining's Smoke and Fumes Committee was excellent. They were extremely cooperative in supplying copies of their committee's actions and keeping him informed otherwise.

D. American Standards Association

Chairman Curtis reported that the American Standards Association activities on the Z-4, Z-37, and Z62 Committees were of direct interest to the Industrial Hygiene Subcommittee. Reports were made directly to the Industrial Hygiene Subcommittee.

E. American Medical Association

J. W. Osborn, M. D., reported that he had been in recent conversation with Dr. Torald Sollmann relative to the AMA Committee on Toxicology's Proposed Conference of Governmental, Industry, and Medicine for the purpose of drafting a model law on labeling of hazardous chemicals. Dr. Sollmann told Dr. Osborn that his committee's original concept of a simple example of a model law when presented to the AMA legal department was rejected as being non-specific. The AMA legal department is now closely studying the proposed laws that are now before Congress. Dr. Sollmann anticipated that his Committee on Toxicology will probably present its recommendations to the AMA Council at its meeting, November 1st and 2nd.

F. Labeling

M. N. Newquist, M. D., reported that the Interdivisional Committee on Labeling has completed an API Labeling Bulletin which will include several recommended labels in addition to the general philosophy of labeling. This Bulletin will be available about the first of the year.

G. First Aid Training

T. M. Frank, M. D., reviewed the activity of the Central Committee on Accident Prevention and its proposed publication of an Administration Guide to help instruct the instructors of first aid training. He indicated that the API First Aid Training Guide was now translated into the Arabic language. There were 1601 qualified first aid instructors from 73 companies.

IV. EXECUTIVE SESSION

A. 1958-1959 Budget

Drinker retain 1958-59

Chairman Curtis explained that the Operating Subcommittee had considered the 1958-1959 Medical Advisory Committee Budget and had recommended it to the Medical and Health Committee in order that it could be presented to the Board of Directors during their November meeting. The following Budget was presented by the Medical and Health Committee and subsequently approved by the Executive Committee and the Budget and Review Committee:

University of Cincinnati	$35,240.00
University of Texas	20,000.00
Prof. Drinker (retainer)	3,000.00
Miscellaneous	1,760.00
Total	$60,000.00

representative.

ACTION: It was regularly moved, seconded, and unanimously passed that Dr. Osborn represent the Medical Advisory Committee if they are called upon to discuss the AMA proposed bill.

F. Labeling

M. N. Newquist, M. D. reported that the API had published Bulletin 2511 on Precautionary Labels in January 1958. It was requested that copies of this Bulletin be sent to the Medical Advisory Committee and Technical Advisors.

G. First Aid Training

T. M. Frank, M. D. reported on the activity in First Aid Training. He indicated that there was considerable interest and activity in this field. The Manual on First Aid Training is being revised.

H. Wax Committee

R. E. Eckardt, M. D. reported that a formal contract had been entered into between the API and The Chicago Medical School for the determination of the toxicity of petroleum waxes. Dr. Philippe Shubik is the director of this project, MC-3. The contract, in the amount of $100,000 for the first year, became effective March 1, 1958.

REE: Wax Comm. signed contract w/Shubik 3/1/58

It was explained that a preliminary investigation of three different kinds of waxes used in milk cartons, as produced by the companies represented by members of the Wax Committee, was being made by Dr. Shubik and his co-workers.

A meeting of the Wax Committee has been called for April 28th in Chicago. At this time, it is hoped that a formal investigational program can be developed and approved.

I. Food Protection Committee

Dr. R. E. Eckardt reported that he had circulated a report to the committee on the activity of the Food Protection Committee. Nothing has occurred since the issuing of this report.

VI. NEW BUSINESS

Dr. Curtis reported that, through the courtesy of Dr. Reeve, his attention had been called to a report made by Dr. Charles P. Mathe, Urologist, St. Mary's Hospital, in San Francisco, to the effect that "workers in oil industries and those coming in contact with dyes show a high incident rate of bladder cancer." The chairman accepted the information on behalf of the committee and agreed to take cognizance of this report with whatever action seemed appropriate to be developed after due consideration.

VII. NEXT MEETING

API 07336

In accordance with the suggestion of the Operating Subcommittee, the Medical Advisory Committee's next meeting will be on Monday morning, November 10th, in the Conrad Hilton Hotel in Chicago. The Subcommittees are to meet on November 7th and 8th. The chairman stated that the request for subcommittee reports be submitted

APPENDIX A

MACs report on staff 1955

HEALTH

A Brief Review of
API Medical Advisory Committee
Activities

American Petroleum Institute
50 West 50th Street
New York 20, N. Y.

API 07338

APPENDIX D

MINUTES OF SUBCOMMITTEE ON ATMOSPHERIC POLLUTANTS MEETING HELD NOVEMBER 8, 1958 IN PRIVATE DINING ROOM 8, CONRAD HILTON HOTEL

Drinker
API
Consultant
November
1958

There were present at the meeting four members of the committee with Professor Philip Drinker as a guest of the committee and also in attendance was Mr. E. O. Mattocks of the API Staff and six additional technical advisory members of the Medical Advisory Committee.

The meeting was called to order by the Chairman and the following business was conducted:

1. The minutes of the previous meeting were approved as distributed. (The previous meeting was held July 10, 1958.)

2. The Chairman submitted the first portion of Dr. Goldblatt's report on Project MC-4. The report consists of 114 pages and is a diary type of his views and impressions of his visit to the United States in June and July. Because of its length and because it is merely a recitation of mainly technical matters the committee felt that it was not ready for distribution to the Medical Advisory Committee and a motion to this effect was passed and the entire report will be circulated when received.

3. The Special Committee consisting of Dr. Clark Miller and Lee Curtis on review of Dr. Goldblatt's expense account to date reported that they now had the expense account of Dr. Goldblatt. Dr. Miller reported that there were areas of expenses that are wrongly included in this account and that they require further auditing, as well as reviews of the entire matter before a definite approval of a true account of expenses can be approved.

4. The Chairman outlined the proposed Rule 62 of the Air Pollution Control District of Los Angeles as submitted for adoption to the Board of Supervisors of Los Angeles County which would outlaw the burning of all fuel oil with exception of steamship lines, railroad lines and diesel motor vehicles which would contain more than 0.5%. It was argued that this change to fuel oil of less than 0.5% sulfur was necessary because any fuel containing more than 0.5% would be a health hazard to the citizens and plant life of the Los Angeles Basin.

The toxicity of sulfur dioxide was discussed fully by all members of the subcommittee, visitors and technical advisors and the conclusion was that a statement be prepared with regard to the health hazards which might become evident if Rule 62 is adopted by the Board of Supervisors of Los Angeles County, California.

This statement would be prepared with the help of Professor Drinker and the members of the committee and would be submitted to the Medical Advisory Committee for approval. However, prior to its approval the Subcommittee on Air Pollutants will ask the chairman to present this to the Technical and Research Division of the Smoke and Fumes Committee as a subcommittee statement. This was passed unanimously.

5. A motion was passed requesting the Medical Advisory Committee to have Report 32 (sulfur dioxide) of the Toxicological Reviews revised to date as it now contains many factual discrepancies.

6. Dr. Hine reported that the Automobile Manufacturers Association subcommittee on the effects of their pollutation on health will institute steps to obtain funds for a research program on the effects of air pollutants on health.

Respectfully submitted,

API 07390

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

b. Medical care in case of nonoccupational injury or illness is not a responsibility of an occupational health program, with the limited exceptions noted below.

Emergency cases should be given the attention required to prevent loss of life or limb or to relieve suffering until the patient is placed under the care of a personal physician.

For minor disorders, first aid or palliative treatment may be given if the condition is one for which the individual would not reasonably be expected to seek the attention of a personal physician, or to enable the individual to complete his current work shift before consulting a personal physician.

In occupational health programs, requests for treatment of repetitive personal disorders should be discouraged, and such individuals should be referred to their personal physicians.

c. The best interests of a patient are served by cooperation and communication between attending physicians and physicians in charge of occupational health programs. In this way, prompt restoration of employees to suitable employment can be assured.

5. Health and safety education. A high standard of occupational health cannot be achieved without familiarity with, and the observance of, fundamental health rules. The development of an understanding of these rules and the promotion of their observance is an essential task in which an occupational health staff can render very valuable assistance.

Worker education stressed

An occupational health program should promote the education of employees in matters of personal hygiene and health and encourage the use of safeguards provided to protect against any hazards to health which may be inherent in their jobs. The most favorable opportunities for carrying on health education and counseling will be afforded during visits to health facilities and through periodic inspections of the employee's place of work.

Health and safety education involves the cooperative efforts of health, safety, and operating personnel. Such education should include not only the encouragement of habits of cleanliness and orderliness but also instruction, in collaboration with the employee's immediate supervisor in safe work practices, in the use and maintenance of available personal protective clothing and equipment.

Experience has shown that health education is unlikely to be successful unless the employer demonstrates his sincere and continuing interest in the health of his employees. This entails participation by health personnel in health and safety meetings. Likewise, employees should be encouraged to participate in the planning and conduct of health education activities and to make full and effective use of occupational health services and facilities available to them.

An occupational health program to be effective and acceptable to the employee, must be staffed by objective and competent personnel who create an atmosphere of warm, sincere, and positive personal helpfulness.

APPENDIX R-1

SUMMARY OF WAX RESEARCH PROJECT

Presented by R.E. Eckardt, M.D.,
Chairman Advisory Committee to Wax Research Project

In August 1956 at a meeting of the Carcinogens in Food Committee of the International Union Against Cancer, Dr. W. C. Hueper of the U.S. National Cancer Institute, U.S. Department of Health, Education and Welfare, stated that coating waxes were suspected of containing carcinogens. This was widely heralded in the lay press and led to a number of inquiries being made of petroleum companies.

Wax research status 11/10/58 *

Upon his return to the United States, Dr. Hueper requested Mr. E. Kellogg, of the Milk Industry Foundation, to collect dairy carton wax samples from a series of dairies in the United States. A total of about 40 such samples were collected. Twenty-four of these were sent by Dr. Hueper to Dr. Philippe Shubik of the Chicago Medical School.

In the Fall of 1957, Dr. Shubik made known to the petroleum industry the results of his investigations of these samples. The ultraviolet (U-V) absorption spectrum of a chromatographed sample from one of the waxes indicated the presence of 1,2,5,6-dibenzanthracene at a concentration of 0.4 microgram per gram of wax. The U-V absorption spectra of 2 other samples suggested the presence of this compound, but the data were not conclusive. As a result of these preliminary studies, the API signed a contract with Dr. Shubik to study waxes which might come in contact with food. This contract called for work by Dr. Shubik at a level of $100,000 per year. The Wax Research Advisory Committee was established by the API to assist and guide Dr. Shubik in the technical phases of wax and to collect samples for him.

To date, some 18 paraffin (macrocrystalline) and 8 microcrystalline waxes have been made available to Dr. Shubik in 100 pound lots for his testing program. No carcinogenic hydrocarbon has been identified to date in any of these 26 wax samples. Chromatography and subsequent U-V absorption spectra of the aromatic fractions have disclosed wide variability, presumably in purity, of the 26 waxes.

Biological tests have been started on several waxes. The one wax sample in which 1,2,5,6-dibenzanthracene was demonstrated has been painted on the skin of mice as a 15% solution in benzene 3 times a week for 43-48 weeks. Although 3 benign tumors have developed, they did not develop in the painted area and are believed by Dr. Shubik to be of no significance. In 3 groups of mice, 0.05, 0.1 or 0.5 gm of this wax has been implanted subcutaneously. No tumors have appeared after 46 weeks.

Five waxes of the 26 supplied by the committee (3 paraffin and 2 microcrystalline) selected on the basis of a wide range of U-V absorption are being subjected to the following biological tests.

1. Mouse skin painting as a 15% solution in benzene.
2. Rabbit skin painting.
3. Mouse subcutaneous implantation.
4. Rat feeding.

All tests to date are negative, but it is much too soon to draw any conclusions.

Wax Comm. hopes to develop Std. acc. to FDA 6/59

G. Wax Committee - R. E. Eckardt, M. D. reported on the activities of this committee. He indicated that the Wax Committee believes their work is progressing satisfactorily. It is their hope that the investigational work will permit the establishment of a standard for petroleum waxes which will be acceptable to the Food and Drug Administration.

H. Quarantine Service - There was no report from this group.

I. Interdivisional Committee on Petroleum Food Additives - L. E. Curtis, M. D. announced a new interdivisional committee had been appointed to study the toxicology of petroleum food additives. Chairman Curtis announced that the newly formed committee had their first meeting. The petrochemical field was excluded from the committee scope. Chairman Curtis indicated that it is possible that his committee will ask the Advisory Committee to the Wax Research Project to include petrolatum in their investigation. Dr. Curtis stated that his committee will ask Mr. Porter to write the various petroleum companies asking that they notify his committee if they have contacted the Food and Drug Administration in regard to any of their problems on petroleum food additives, provided such problems are of mutual interest to the whole petroleum industry.

VI. TENTATIVE BUDGET FOR 1960-61

Air Pollution	$ 5,000.00
C_9 - C_{12} Aromatics	20,000.00
Treatment for Kerosine Ingestion in Children	7,500.00
Research on Noise in Industry	5,000.00
Consulting Services	3,000.00
Toxicological Reviews	10,000.00
Administrative Services	1,500.00
TOTAL	$52,000.00

ACTION: It was regularly moved, seconded, and unanimously passed that the tentative budget be approved, subject to final review at the 1959 Fall meeting.

VII. NEXT MEETING

The Operating Subcommittee recommended that the next meeting of the Medical Advisory Committee be held Monday morning, November 9, 1959, in the Conrad Hilton Hotel, Chicago, Illinois, during the Annual API Meeting. The subcommittee meetings will be scheduled on Friday and Saturday, November 6 and 7 with the Operating Subcommittee to meet Sunday P. M., November 8th, and the Round Table Session to be held Monday P. M., November 9th.

ACTION: It was regularly moved, seconded, and unanimously passed that the recommendation of the Operating Subcommitte be approved.

VIII. NEW BUSINESS

1. Reception - F. F. Boys, M. D., Sinclair Refining Company, requested Chairman Baird to announce that the Sinclair Refining Company was giving a reception for N. J. Gothard who has been a Technical Advisor to the Medical Advisory Committee since the committee was formed in 1945. Mr. Gothard is to be retired in the near future.

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.

Wax sent by API to Shubik had no known carcinogen 1959

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.

Secretary of HEW: no dibenzanthracene in waxes tested for API by Shubik

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

API 07581

Wax time extension Mtg Oct API from (FDA)

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.
R. O. Mattocks

Copy From R. 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

API 07583

FOR COMMITTEE USE ONLY NOT FOR PUBLICATION

MEDICAL ADVISORY COMMITTEE
29TH MEETING

April 25, 1960
Council Room, The Manger Hotel
Rochester, New York

MEMBERS PRESENT:

J. W. Osborn, M. D., Chairman
Leo J. Wade, M. D., Vice Chairman
L. E. Renes, Secretary

W. O. Armstrong, M. D.
V. C. Baird, M. D.
(Rep. by E. R. Herman)
C. H. Baylor, M. D.
R. G. Birrell, M. D.
(Rep. by E. A. Turcot)
F. F. Boys, M. D.
G. H. Collings, M. D.
Kieffer Davis, M. D.
(Rep. by Paul Heerwagen, M. D.)
R. E. Eckardt, M. D.
T. M. Frank, M. D.
T. J. Kelly, M. D.
E. K. Linder, M. D.
C. R. Miller, M. D.
T. H. Mitchell, M. D.
J. C. Ruddock, M. D.
G. M. Saunders, M. D.
(Rep. by A. C. Pabst)
Ralph Schneider, M. D.
W. Wayne Stewart, M. D.

TECHNICAL ADVISORS PRESENT:

W. H. Barcus
E. K. Daniels
A. E. Dooley
Geo. Entwistle
H. W. Gerarde, M. D.
J. H. Johnston
P. K. Kuhne
C. A. Neilson
A. C. Pabst
Jack Spence
(Rep. by G. M. Wilkening)
N. K. Weaver, M. D.

MEMBERS ABSENT:

R. M. Adams, M. D.
T. E. Allen, M. D.
J. W. Crookshank, M. D.
L. E. Curtis, M. D.
K. R. Fourcher, M. D.
F. D. Gassaway, M. D.
R. Emmet Kelly, M. D.
E. P. Luongo, M. D.
B. S. Miller, M. D.
R. C. Page, M. D.
R. J. Potts, M. D.

OTHERS PRESENT:

Philip Drinker, Consultant	-	Harvard University
E. O. Mattocks	-	American Petroleum Institute
Lloyd Pickett, M. D.	-	Gulf Oil Corporation
Enrique Quino	-	Esso Standard
John R. Scott, M. D.	-	Carter Div., Humble Oil & Refining Co
H. van Raalte, M. D.	-	Royal Dutch Shell (The Hague)
Robert A. Wise, M. D.	-	Humble Div., Humble Oil & Refining Co.

Drinker
Consultant
1960

F. Wax Committee - R. E. Eckardt, M. D., chairman of the Advisory Committee to the Wax Research Project, reported on the activity of this group. In summary, the Advisory Committee has (1) submitted data with recommendations to the Food and Drug Administration for clearance of a Type 1 wax and a request for a year's extension of a Type 2 wax, (2) established an Analytical Subcommittee which has prepared an ASTM Method for determining the absorptivity of waxes. The group is also studying the need to standardize other tests used in complying with the FDA wax specifications. (3) started additional feeding tests to continue the study on Type 2 waxes, and (4) planning to continue the wax research project at the same level of expenditure of $150,000 per year. (5) received an extension of a year from the FDA for Type 1 and Type 2 petroleum waxes.

Wax
rept.
on FDA
moves to
develop
regulation
1960

G. Quarantine Service, The U. S. Public Health Service - No report.

H. Interdivisional Committee on Petroleum Food Additives - No report.

V. BUDGET FOR 1961-1962

The following budget was proposed:

Atmospheric Pollutants	$ 5,000
C9 - C12 Aromatics	10,000
Noise	2,500
Specialty Petroleum Products	15,000
Toxicological Reviews	5,000
Consultant	3,000
Administrative Expense	1,000
	$41,500

ACTION: It was regularly moved, seconded, and unanimously passed that a budget of $41,500 be recommended to the Medical and Health Committee for the year 1961-1962.

VI. NEXT MEETINGS

The next meeting of the Medical Advisory Committee will be held in conjunction with the Annual Meeting of the API in Chicago on November 11, 12, 13, and 14, 1961.

It was indicated that the Industrial Hygiene Association is planning to hold its spring meeting at a time and place different from the spring meeting of the Industrial Medical Association in 1961. At this time, the Industrial Medical Association had indicated that they are planning to hold their meeting in Los Angeles on April 11, 12, 13, and 14, 1961. The Industrial Hygiene Association group is tentatively planning to hold their meeting in Detroit on April 18, 19, and 20, 1961.

ACTION: It was regularly moved, seconded, and passed that, assuming the IMA spring meetings are held as now indicated and the IHA spring meetings are held as indicated, the Medical Advisory Committee and its subcommittees hold their spring meetings in Detroit on the 15th, 16th, and 17th of April, 1961. There were 22 for this motion and 4 against.

(Secretary's Note: Since this action, the meeting dates of the IMA and AIHA have been changed. Because it is necessary to make meeting room arrangements at the earliest possible moment, the date of the MAC and Subcommittee meetings must be established as soon as possible. The chairman will announce the time and place of these meetings in the very near future.)

APPENDIX M

1960 REPORT OF THE ADVISORY COMMITTEE TO THE WAX RESEARCH PROJECT TO THE MEDICAL & HEALTH COMMITTEE

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

Because little reliable information was available on the possible toxicity of petroleum waxes, the Board of Directors authorized, in 1957, the establishment of an investigation on the toxicity of petroleum waxes. The research project was initiated at the beginning of 1958. This far-sighted move proved exceedingly helpful when, in September 1958, the President of the United States signed into law the Food Additives Amendment. This amendment requires that the producer or marketer of a food additive must show to the full satisfaction of the U. S. Department of Health Education, and Welfare that the food additive under question is not harmful to man or animals.

Still no decent analytical method for reg. use

1960 Wax Rpt

The investigation of possible toxicity of petroleum waxes has been under study continuously at The Chicago Medical School, under the direction of an internationally known expert on cancer, Dr. Philippe Shubik.

Based on the findings at The Chicago Medical School, sufficient information was obtained to permit the Department of Health, Education, and Welfare to grant a year's extension to the use of two groups of petroleum waxes: type 1, which is essentially paraffin wax, and type 2, which is essentially microcrystalline wax. This extension expires March 6, 1961. It will be necessary for the industry to petition the Department of Health, Education, and Welfare before this time and request an approval of petroleum waxes.

The investigational work at The Chicago Medical School has not yet been completed, nor is it expected that it will be completed by March 6, 1961. The findings to date indicate that there should be no difficulty in obtaining an outright approval for the use of petroleum waxes as an incidental food additive. While the use of waxes as a food additive was justified from the experimental results, nevertheless, additional experimental investigations have been necessary to clarify beyond any doubt certain unexplained conditions which appeared during the biological testing. The experimental work is proceeding well and should be essentially completed in about one year.

The committee is planning to formally request, before March 6, 1961, approval for the use of petroleum waxes after that date.

The cooperation of the petroleum analysts has been obtained in the development of a satisfactory analytical method for use with petroleum waxes. The one developed by The Chicago Medical School, while highly satisfactory and extremely accurate, is time consuming. The use of such a method in plant control work or by the Food and Drug Administration people in their inspection work is extremely doubtful. Great effort is being made by various petroleum industry laboratories to develop a control type of analysis which will still have incorporated within it the desired accuracy, but which can be performed in a reasonable length of time.

In anticipation of the financial requirement of the wax investigation, the 1961 budget of the API contains an item of $150,000 to continue the wax research project for another year. However, a careful review of future requirements indicates that only $100,000 will be needed. Therefore, the budget can be reduced by $50,000.

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

The nature of the study reflects the general feeling of those making suggestions and also reflects the opinion of the subcommittee.

Investigation as to facilities available and costs have been very limited because of the time the subcommittee has had. The subcommittee has not wished to proceed too far without some specific approval by the MAC. Based on the limited information at hand, we feel that a program which will be acceptable to the MAC can be developed for the amount requested.

While we have recommended that the Goldblatt project be terminated, the subcommittee believes that the work should be continued and that a review of current literature be made. In order to accomplish this, to be of help to this subcommittee and to the MAC, the following recommendations are presented for MAC consideration:

A. That $5,000 be budgeted for the services of a technical consultant.

B. That the $5,000 available for the year 1961 be used for the services of a technical consultant, for the year July 1, 1961 to June 30, 1962.

C. That, pursuant to adoption of A above, Dr. Philip Drinker be engaged as this technical consultant.

Drinker remains API Consultant 1961-62

As a matter of information, agreement has been reached for the subcommittee to meet with a comparable group of the Automobile Manufacturers Association. The subcommittee will report on this meeting in November.

C. L. Samuelson, M. D., Chairman

APPENDIX L

Wax
regs
delayed
1961

ADVISORY COMMITTEE TO THE WAX RESEARCH PROJECT - LIAISON REPORT TO MEDICAL ADVISORY COMMITTEE

In the absence of Dr. Eckardt, Chairman, I am happy to submit a brief report of the activities of the API Wax Research Project.

In accordance with the new Food Additives Law, a petition was filed in February this year with the Food and Drug Administration for a regulation which would permit the use of certain waxes in connection with food. In a sense, the petition was incomplete because (1) some of the two-year animal studies have not been completed and the data submitted on this portion of the work, although factual, undoubtedly will not be accepted before the two-year period is up; and (2) a very short and proper analytical method for testing waxes has not yet been devised. The method submitted as a part of the petition is a lengthy one requiring days for completion. From past experience, the Food and Drug people will desire to have an analytical method that will require only a few hours for completion.

On the basis of a letter from the Food and Drug Administration, petroleum waxes are now eligible for an extension of time, since the enactment of the transitional amendment to the Food Additives Law. We are confident that the data already developed, plus that which will result from the long-term animal experimental work and a concise analytical method for testing waxes which will be resolved before long, will allow this research group to present a completed petition that will be accepted by the Food and Drug Administration, to the end that a regulation will be written for the use of certain waxes in connection with food.

Presented by:
George Saunders, M. D.
MAC Liaison Member

Chairman Osborn announced the following changes in the Medical Advisory Committee membership since the spring meeting, April 8, 1961: R. F. Schneider, M. D., new vice chairman, replacing Leo J. Wade, M. D., who resigned; L. W. Sanders, M. D., Ethyl Corporation, new member; Stewart L. Rankin, M. D., E. I. du Pont de Nemours Co., new Member; R. R. Dugan, M. D., Continental Oil Company, new member, replacing W. O. Armstrong, M. D., retired; R. M. Adams, M. D., formerly with Interstate Oil Pipe Line Company, now with Humble Oil & Refining Company; T. M. Frank, M. D., American Oil Company, deceased; George Wilkening, Technical Advisor, now located in Humble's Houston office; and T. J. Smith, M. D., Technical Advisor, American Oil Company, retired.

II. APPROVAL OF MINUTES

ACTION: It was regularly moved, seconded, and unanimously passed that the minutes of the April 8, 1961, meeting be approved as distributed.

III. CERTIFICATES OF APPRECIATION

Mr. C. E. Spahr, chairman of the Medical and Health Committee of the Board of Directors, presented Certificates of Appreciation to L. E. Curtis, M. D. and J. M. Saunders, M. D., whose certificate was received by Mr. A. C. Pabst. A Certificate of Appreciation for T. M. Frank, M. D. is to be given posthumously to Mrs. Frank by a representative from the American Oil Company.

IV. SUBCOMMITTEE REPORTS

A. Operating Subcommittee

The chairman presented the actions of the Operating Subcommittee, Appendix A, which met on November 11, 1961.

ACTION: It was regularly moved, seconded, and unanimously passed that the minutes of the November 11, 1961, meeting of the Operating Subcommittee be approved, including the actions recommended by this group.

B. Atmospheric Pollutants

C. L. Samuelson, M. D., chairman of the Subcommittee on Atmospheric Pollutants, presented his report which is attached as Appendix B. This subcommittee is recommending that the research project proposed by the Chicago Medical School, under the direction of Philippe Shubik, M. D., be approved.

ACTION: It was regularly moved, seconded, and unanimously passed that the report of the Subcommittee on Atmospheric Pollutants be approved.

Shubik rec. for more API research work

Dr. Samuelson reported on his appointment to a committee of the Public Health Service concerned with the surveys to determine the lead content of the air and the lead burden of humans, being conducted by the Department of Health, Education, and Welfare at Cincinnati, Philadelphia, and Los Angeles. The API is financially assisting the survey being conducted at Cincinnati.

C. C_9 - C_{12} Aromatics

API 07710

Kieffer Davis, M. D., chairman, presented the report of his subcommittee which is attached as Appendix C.

APPENDIX E

REPORT OF THE SUBCOMMITTEE ON INDUSTRIAL HYGIENE

Dr. J. A. Spence, Chairman

1 Hasp. of petrol. refining rept 1962

The Subcommittee on Industrial Hygiene met on November 11, 1961, with six members, Professor Drinker as consultant, and eight guests present.

Liaison members to the American Standards Association committees reported there had been no recent activities on the Z-62, Z-37, and Z-4 Committees

It is planned that the project report, "The Industrial Hygiene Aspects of Petroleum Refining," will be submitted to the Medical Advisory Committee at the Spring 1962 meeting.

In connection with the study on C_9 - C_{12} Aromatics, the subcommittee plans to review the major marketing uses of the C_9 - C_{12} type aromatic products. If indicated, a study will be considered to determine whether the present industrial uses of these products are hazardous to health.

The status of the U.S.P.H.S. Lead-in-Air study was reviewed by Dr. Samuelson. No action was required by the Subcommittee on Industrial Hygiene.

The present status of the U.S.P.H.S. Study on Oil Mists was reported by Mr. Dooley. No action was requested from the subcommittee.

Effective January 1961, Federal Standards for Safety and Health were established under the Walsh-Healey Act. Mr. Wm. Avrett was appointed as subcommittee liaison member to serve with other industry groups interested in this act. He reported that on November 7, the Manufacturing Chemists' Association submitted suggestions to modify requirements covering toxic materials in the working environment. It was also pointed out that the Manufacturing Chemists' Association would like to be informed if any company is inspected under the Walsh-Healey Act by a government inspector.

Dr. J. A. Spence, Chairman

APPENDIX M

1961 REPORT OF THE ADVISORY COMMITTEE TO THE WAX RESEARCH PROJECT TO THE MEDICAL AND HEALTH COMMITTEE

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

The Advisory Committee to the Wax Research Project met in Chicago on November 1, 1961. At that time, the final report of the biological work conducted by the Chicago Medical School, under the direction of Dr. P. Shubik, was received. Effort will be made to file a petition with the Food and Drug Administration for approval of the use of petroleum waxes as food additives by the first of 1962. If this is not possible, it will be necessary that a request for an extension for another six months be made to permit the use of petroleum waxes until such time as the petition can be prepared and filed.

In essence, these studies showed that the feeding of five different waxes at levels of 10% in the diet of rats for two years resulted in no significant tumor or cancer production. Previously reported skin painting studies in mice and rabbits, and subcutaneous implantation studies in mice had revealed no cancer-producing potential for these waxes, except for sarcoma production by implantation. Recent experiments demonstrated that this was the result of a physical property of the waxes, rather than a chemical property. Similar physical properties are exhibited by certain plastics (Teflon cellophane, etc.) and by glass. Thus, it is felt that these biological studies have conclusively demonstrated that there is no hazard to the public from the use of waxes as components of food or food packages. It is on this basis that the petition will be worded.

Sarcoma from Wax implants

FDA wants test of Wax contaminants

Analytical studies by the Chicago Medical School, materially helped and assisted by an Analytical Subcommittee of the Advisory Committee to the Wax Research Project, will permit the submission of a suitable analytical method as a part of our petition. It is believed that this method will permit adequate quality control of waxes to satisfy the requirements of the Food and Drug Administration.

The Advisory Committee to the Wax Research Project believes that, upon the issuance of a favorable regulation by the Food and Drug Administration on waxes, its work will have been brought to a successful termination and that there will be no further need for its existence. However, it is possible that the Food and Drug Administration will not issue a favorable regulation for the use of wax. In accordance with the law at that time, the wax petition was filed March 1, 1961 with the Food and Drug Administration, although the biologic testing was not complete. The Food and Drug Administration indicated that the petition was not acceptable because of the absence of sufficient data to permit an evaluation of the safety of petroleum waxes as a food additive. They, likewise, requested that biologic tests be conducted on minute quantities of hydrocarbons which had been found in certain petroleum waxes. These hydrocarbons have been quoted in literature as being suspected of forming cancer. While the literature references were of uncertain value and did not relate to their use as a food additive, it appeared that the Food and Drug Administration expected the American Petroleum Institute to run biologic tests to prove whether or not they were cancer forming when used as a food additive. It was after receipt of this request that the Advisory Committee to the Wax Research Project recommended $100,000 be placed in the 1962 budget to continue the wax investigation.

Following the filing of the wax petition, the Congress of the United States modified the Food Additives Law to permit granting of further extensions in those cases where investigational work had not been completed. After this action by Congress, the American Petroleum Institute petition was withdrawn. The chief

[redacted]

nvestigator of the wax project, Dr. Philippe Shubik, and the Wax Committee are firm in heir belief that the American Petroleum Institute should not undertake the long and expensive biologic testing requested by the Food and Drug Administration. We believe that when the current investigational program is completed, that the petroleum industry will have complied with the Food Additives Law and the petroleum industry should be prepared to stand on this decision. It may be necessary to resort to legal means to support these rights. The Program and Budget Review Committee reduced the $100,000 recommended by the Wax Committee to $50,000, which amount is now in the 1962 budget. This money may be needed to conduct further biologic tests or to finance legal assistance, if these are needed.

API + Shubik oppose testing w/ax contaminants (pref to let lawyers get FDA OK)

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

[redacted]

November 14, 1961

APPENDIX I

REPORT OF SUBCOMMITTEE ON TOXICOLOGICAL REVIEWS

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

The subcommittee met in Private Dining Room 19 in the Conrad Hilton Hotel, on Friday afternoon, November 9, 1962.

A number of guests were present in addition to members of the subcommittee.

Since the April meeting, toxicological reviews have been published on Styrene, Cyclohexane, Sulfur Dioxide and Sulfuric Acid.

The subcommittee is currently preparing drafts on Aromatic Petroleum Naptha, Cumene, and Kerosine for distribution to members of the Medical Advisory Committee.

Professor Drinker will be asked to prepare a toxicological review on gasoline. The subcommittee requests that the API pay him in advance for his services. The chairman and one or more members of the subcommittee will personally call on Dr. Ralph Smith, of Wayne University, to discuss his proposal that Gasoline, Stoddard Solvent and Petroleum Naphtha be defined and listed as petroleum distillates in the ACGIH MAC tables.

(Drinker preparing tox. rev. on gasoline for API)

API group mtg. w/ ACGIH group re MACs for gasoline etc

The subcommittee felt that the term "Petroleum Distillate" was not in common use outside of the petroleum industry. The list of petroleum distillates with various distillation ranges and aromatic content is large and hence its use would create more misunderstanding and confusion than the present classification and terminology.

I move the adoption of this report.

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

APPENDIX P

REPORT OF THE ADVISORY COMMITTEE TO THE WAX RESEARCH PROJECT
TO THE
GENERAL COMMITTEE, DIVISION OF SCIENCE AND TECHNOLOGY

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

Wax as direct & indirect food additive

A petition was filed with the Food and Drug Administration of the Department of Health, Education, and Welfare, on June 4, 1962, to permit the use of petroleum waxes as food additives: a, as a direct food additive in chewing gum and other confections, an anti-frothing agent in sugar and for the waxing of fruits and vegetables; and b, as an indirect additive in or on materials used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food. This petition was subsequently amended on June 19 and June 22. Subsequently, the FDA indicated they wished additional information. Following a conference, Mr. Porter supplied, on October 2nd, the additional information requested and filed two additional amendments to the petition. The petition was formally filed September 27, 1962. It is hoped that within a reasonable length of time a regulation will be issued permitting the use of petroleum waxes as food additives.

The petition is based on experimental work done by the Chicago Medical School, under the direction of Philippe Shubik, M. D. $523,000 has been spent so far. While there is still a small amount of biological research being done by the Chicago Medical School as a follow-up, essentially, the investigational work is completed. No money was requested for 1962.

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

November 12, 1962