

A Summary of the Draft Phase II Fernald Risk Assessment Report

Screening Level Estimates of the Lifetime Risk of Developing Kidney Cancer, Female Breast Cancer, Bone Cancer, and Leukemia as a Result of the Maximum Estimated Exposure to Radioactive Materials Released from the Fernald Feed Materials Production Center (FMPC)

BACKGROUND

Fernald Risk Assessment Project

Draft risk estimates provided to the community in August 1996 from the Fernald Dosimetry Reconstruction Project (FDRP) did not provide a comprehensive summary of the potential health effects of the Fernald Feed Materials Production Center (FMPC) on residents in the surrounding community. Many individuals, who could not relate their own experiences to those defined in the nine exposure scenarios provided in the Fernald Dosimetry Reconstruction Project Report were left with questions about their risk. Because of this, CDC proposed to analyze human health risk for the community surrounding the FMPC using model-based risk estimation. This approach would provide a summary estimate of the number of selected disease outcomes that could potentially occur due to exposure to radioactive materials released from the FMPC during its operating years (1951-1988). The results of this risk assessment also will be used to help determine the scientific feasibility of an epidemiologic study in the Fernald community. The first phase of our risk assessment project focused on evaluating the effect of FMPC-related radiation exposures on the risk of lung cancer death in the community surrounding the FMPC site. The final results of the lung cancer mortality risk assessment were released in December 1998 in a report entitled *Estimation of the Impact of the Former Feed Material Production Center (FMPC) on Lung Cancer Mortality in the Surrounding Community*. The main result given in this report was our estimate that the number of lung cancer deaths among the assessment population may increase by 1% to 12% as a result of exposure to radioactive materials, primarily radon and radon decay products, released from the FMPC site from 1951 through 1988.

THE FOCUS OF THE PHASE II REPORT

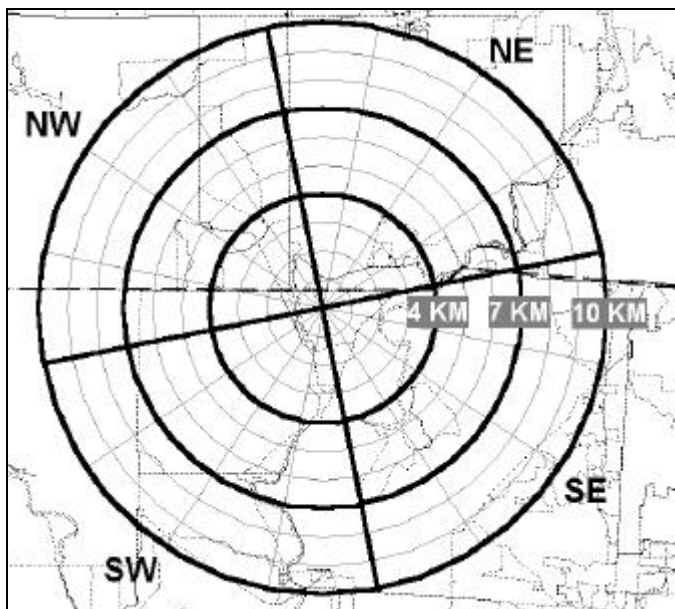
The June 1999 Phase II Fernald Risk Assessment Report contains screening level estimates of the lifetime risk of developing kidney cancer, female breast cancer, bone cancer and leukemia. These screening level estimates differ from the lung cancer mortality estimates presented in the Phase I report because they reflect our attempt to estimate the upper bound or "worst case" number of cases of these types of cancers that may have occurred or may occur among residents of the Fernald area as a result of exposure to radioactive material released from the FMPC during the plant's production years. In the Phase I report, we estimated the actual, as opposed to worst case, number of lung cancer deaths that could result from this exposure. The upper bound estimates provided in the Phase II report can provide area residents with a reference point for evaluating their own potential FMPC radiation-related cancer risk. In addition, the results of both phases of the Fernald Risk Assessment Project will be used to help focus future CDC research and public health activities related to past radiation exposure in the Fernald community.

Key Results

- ◆ We estimate that approximately 46,000 individuals resided within the assessment domain (within 6.2 miles or 10 kilometers of the FMPC site) for any amount of time from 1951 through 1988.
- ◆ We estimate an upper bound (or worst case number) of 23 or less additional cases of leukemia among the approximately 46,000 people who resided within the assessment domain sometime from 1951 through 1988 as a result of exposure to radiation released from the FMPC during that period.
- ◆ We estimate an upper bound (or worst case number) of 4 or less additional cases of kidney cancer, 3 or less additional cases of female breast cancer, and 4 or less additional cases of bone cancer among the approximately 46,000 people who resided within the assessment domain sometime from 1951 through 1988 as a result of exposure to radiation released from the FMPC during that period.
- ◆ These upper bound, or worst case, estimates are based on the unrealistic assumption that all persons who resided within 10 kilometers of the facility received a maximum dose. The actual number of cases that may occur as a result of radiation exposure from the FMPC is likely to be lower than the upper bound estimate.
- ◆ The maximum kidney dose is likely to be lower than 0.2 sieverts for residents of the assessment domain.
- ◆ The maximum breast dose is likely to be lower than 0.02 sieverts for residents of the assessment domain.
- ◆ The maximum bone surface dose is likely to be lower than 1.5 sieverts for residents of the assessment domain.
- ◆ The maximum bone marrow dose is likely to be lower than 0.30 sieverts for residents of the assessment domain.

Recommendations

- ◆ CDC will consult with the Fernald Health Effects Subcommittee to determine if further analyses of the risk of leukemia associated with past exposure to radioactive material released from the FMPC site should be pursued.
- ◆ Because the upper bound estimates for the number of kidney cancer, female breast cancer, and bone cancer cases that may result from exposure to FMPC-related radiation are small, CDC does not recommend a more detailed analysis of the potential FMPC radiation-related risk for these health outcomes.



The Assessment Domain

This figure shows the geographic study area we used in the Fernald Risk Assessment Project. It captures what is termed as the “assessment population”— defined as people who resided within a radius of 10 kilometers (6.2 miles) of the center of the FMPC production area for some period of time between the years 1951-1988.

The area is subdivided into 12 smaller regions based on direction and distance from the site. We estimated the maximum dose to the kidney, breast, bone surface and bone marrow for a hypothetical individual in each of these geographic areas.

We estimate that 39,000 to 54,000 individuals lived in the assessment domain during the plant’s operating years, 1951-1988.

SUMMARY OF KEY RESULTS

This table shows the upper bound estimates for the number of cases of selected cancers that may result from exposure to radioactive material released from the FMPC site among persons who lived within 10 kilometers (6.2 miles) of the facility for any length of time from 1951 through 1988 (including exposure to contaminated well water).

TYPE OF CANCER	Expected Number of Background Cases ^{# @ b}		Upper Bound Estimate for Number of Cases Related to FMPC Radiation Exposure ^{# @}	
	Median*	(90% Credibility Interval)**	Median*	(90% Credibility Interval)**
Kidney Cancer	367	(311 – 435)	1	(0 – 4)
Breast Cancer	2,296	(1,945 – 2,717)	1	(0 – 3)
Bone Cancer	32	(27 – 38)	1	(0 – 4)
Leukemia	367	(311 – 435)	5	(3 – 23)

[#] The median value for the estimated number of persons who resided in the assessment domain for any length of time from 1951 through 1988 is 45,909 with a 90% credibility interval of 38,896 to 54,343. For evaluating the estimated number of female breast cancers, the median estimated number of women in this population is 22,955 with a 90% credibility interval of 19,448 to 27,172.

[@] The number of cases have been rounded to the nearest whole number. For example, if the number of cases is less than 0.5, then the number of cases is rounded to 0.

^b The “number of background cases” is the number of cancer cases expected in this population if there had been no exposure to radioactive materials released from the FMPC.

* 5,000 possible values for the upper bound on the number of cases and the background number of cases were produced to reflect the uncertainty associated with these values. The median is that value greater than one half of the estimates and less than the other half.

** 90% of the 5,000 estimates fall between the upper and lower limits of the 90% credibility interval.

WHAT DO THESE RESULTS MEAN?

The table on page 2 illustrates two sets of numbers. The first two columns of numbers show the number of cases of cancer we would expect in the assessment population in the *absence of any radiation exposure from the FMPC* (Expected Number of Background Cases). The last two columns on the right show the upper bound estimates for the number of cancer cases estimated to be related to FMPC radiation exposure.

As shown under the “Expected Number of Background Cases” category, if the FMPC facility did not exist, 367 kidney cancer cases, 2,296 female breast cancer cases, 32 bone cancer cases and 367 leukemia cases would be expected to occur during the lifetimes of the approximately 46,000 people who lived within the assessment domain sometime from 1951 through 1988 because of their background risk of these cancers.

As shown in the “Upper Bound Estimate...” columns, we estimate that it is likely that 4 or less additional cases of kidney cancer, 3 or less additional cases of female breast cancer, and 4 or less additional cases of bone cancer may occur in the assessment population as a result of exposure to radioactive material released from the FMPC site from 1951 through 1988. Similarly, we estimate an uppermost bound of 23 additional cases of leukemia may result from exposure to radioactive material released from the site among persons who lived within 10 kilometers (6.2 miles) of the facility for any length of time from 1951 through 1988. We use the term *additional* when describing these upper bound estimates of the number of potential FMPC radiation-related cancer cases to emphasize that they are in addition to the background number of cases of these types of cancer that we would expect in this population if the FMPC had never existed.

We define our upper bound, or worst case, estimate for the number of cancer cases as the upper limit of the 90% credibility interval. By using this definition for upper bound, and because we assumed all persons received a maximum radiation dose, the actual number of cancer cases that may occur in the assessment population as a result of FMPC-related radiation exposure is likely to be lower than the estimates presented in this report.

Why we Provide a Range of Numbers

Because we cannot measure actual organ doses nor count the actual number of cancers that result from exposure to radioactive materials from the former FMPC, the estimated number of FMPC radiation-related kidney cancer, female breast cancer, bone cancer and leukemia cases must be made using mathematical models. Because these mathematical models are uncertain, we produce a collection of possible values for the estimated doses and risks. This collection of possible values is summarized using the median and the 90% credibility interval.

In general, to come up with these results, we summarized the collection of estimates derived during thousands of computer “runs.” The median is that value greater than one half of the estimates and less than the other half.

90% of the estimates fall between the upper and lower ends of the 90% credibility interval (sometimes called the uncertainty range).

QUESTIONS AND ANSWERS

WHAT DO YOU MEAN BY SCREENING LEVEL ESTIMATES OF LIFETIME RISK?

We refer to these estimates as screening level estimates because we have tried to develop a “worst case scenario” in order to evaluate the cancer risk for a hypothetical individual who received a plausible maximum FMPC-related radiation dose. We translated our risk estimates for hypothetical individuals into an upper bound or worst case estimate of the number of cases of kidney cancer, female breast cancer, bone cancer and leukemia that may have occurred or may occur in the community as a result of FMPC radiation-related exposures. Our purpose in developing these screening level estimates was to provide residents with a reference point to evaluate their own potential FMPC radiation-related cancer risk and to guide CDC in future research and public health activities.

WHAT DO YOU MEAN BY “THE UPPER BOUND ESTIMATE OF THE NUMBER OF CANCER CASES”?

The upper bound estimates of the number of cancer cases are “worst case” estimates of the number of cases that may occur over the lifetimes of the population exposed to radioactive materials released from the site during its production years. These upper bound estimates are based on the unrealistic assumption that all persons who resided within 10 kilometers of the facility received a maximum dose. The actual number of cases that may occur is likely to be lower than this upper bound estimate.

WHY DOES THIS SCREENING LEVEL RISK ASSESSMENT ONLY FOCUS ON KIDNEY CANCER, FEMALE BREAST CANCER, BONE CANCER AND LEUKEMIA?

These four health outcomes were chosen for this report because they are perceived by the community to be related to past releases of radioactive materials from the FMPC. Also, biologic and other scientific evidence suggests that these cancers may be associated with the types of radioactive material released from the site from 1951 through 1988.

IS IT POSSIBLE THAT THE HYPOTHETICAL MAXIMALLY EXPOSED INDIVIDUALS IN THE REPORT COULD REPRESENT A REAL PERSON WHO LIVED NEAR THE SITE?

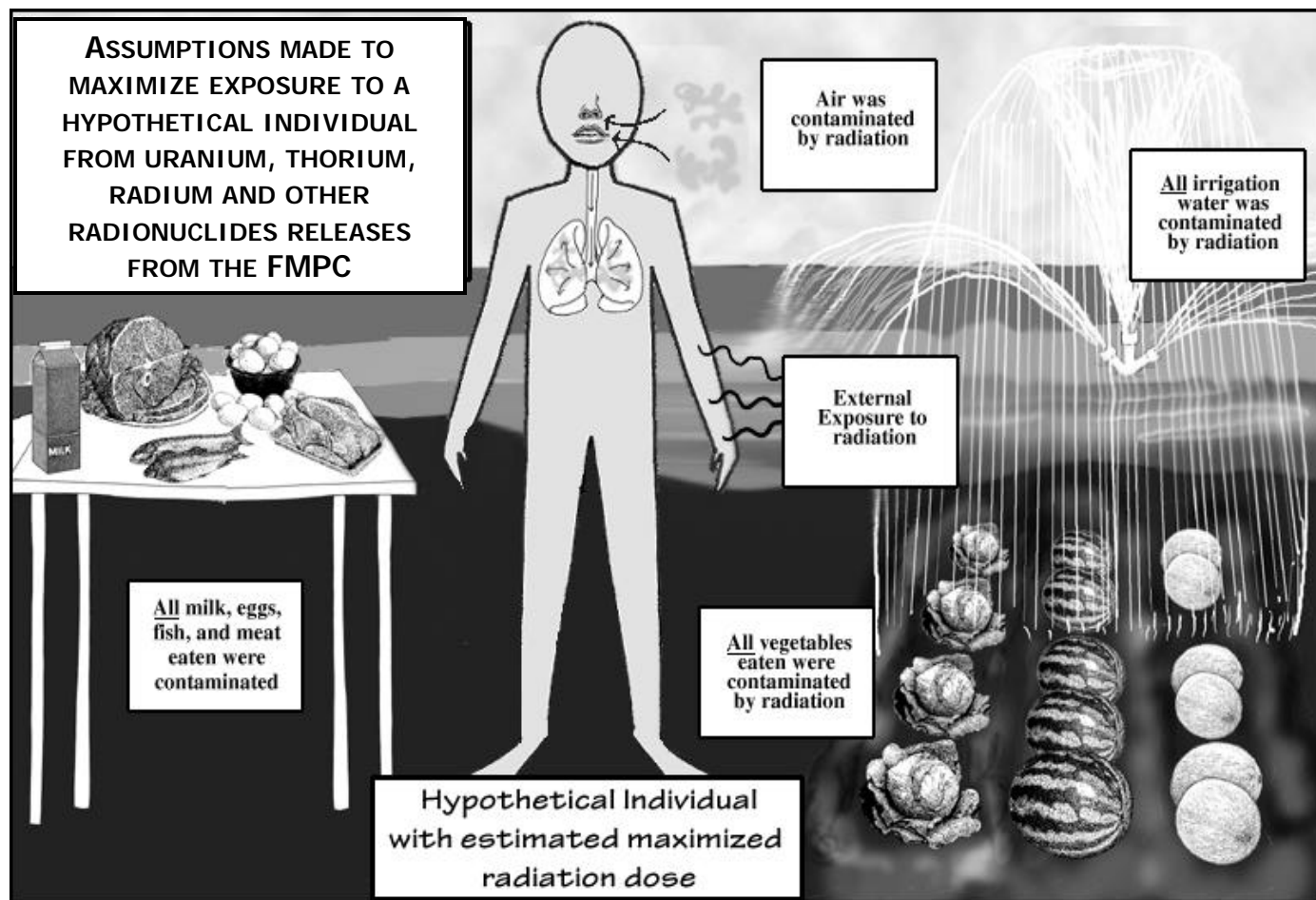
It is possible, but unlikely. Consider some of the assumptions which were made to determine the risk of a hypothetical maximally exposed individual during the time period 1951-1988:

- *Every single vegetable eaten by this individual was considered to be contaminated.*
- *All milk consumed by the individual was considered contaminated.*
- *All beef and chicken eaten were assumed to be contaminated.*
- *Every single egg eaten was considered to be contaminated.*
- *All fish eaten were assumed to be contaminated.*

HOW WAS THE WORK DONE?

This report provides screening level estimates of the lifetime risk of developing kidney cancer, female breast cancer, bone cancer and leukemia from the maximum or largest plausible exposure from radioactive materials released from the site from 1951 through 1988. Screening level estimates of the maximum doses and lifetime risks were made for 12 hypothetical individuals assumed to have lived in different areas within 10 kilometers (6.2 miles) of the site for some period of time from 1951 through 1988.

To maximize the dose estimates for these hypothetical individuals, we made assumptions about a number of lifestyle characteristics that do not likely reflect the true lifestyle characteristics of the majority of the assessment population. For example, we assumed that radioactive materials from the FMPC contaminated all meat and eggs eaten by these individuals (see the figure below for an example of one of our “hypothetical “ individuals).



We estimated the risk of cancer *occurrence* that includes both fatal and nonfatal cancers.

We translated our risk estimates for hypothetical individuals into an upper bound, or worst case, estimate of the number of each of these cancers that may occur among residents of assessment domain as a result of FMPC radiation exposure. These are upper bound estimates because they are based on the unrealistic assumption that all persons who lived within any of the 12 areas of the assessment domain for any length of time from 1951 through 1988 received the estimated maximum lifetime dose for that area.

IMPORTANT NOTE:

The numbers presented in this table and summary text are not exact estimates. We cannot *prove* that FMPC-related exposures caused or will cause anyone to develop cancer— in either the community or specific individuals. Our work is a prediction of the chance of such an effect.

DIFFERENCES BETWEEN THE PHASE I AND II FERNALD RISK ASSESSMENT REPORTS

The key difference between the two reports is that this Phase II report provides screening level estimates of the lifetime risk of developing kidney cancer, female breast cancer, bone cancer, and leukemia for persons who received a plausible value for the maximum exposure to radioactive materials released from the FMPC during its operating years. These estimates present a worst case scenario for the risk and number of cancer cases that could result from FMPC radiation exposures. They are based on lifestyle assumptions that will maximize estimated exposures (e.g., all meat consumed was assumed to be contaminated by radioactive materials from the site).

The goal in the Phase I lung cancer report was much different. It provided estimates of the lung cancer mortality risk. Its purpose was not to estimate an upper bound for the community's risk, but rather to estimate the range of possible FMPC-related lung cancer mortality risks that actually may occur based on realistic assumptions about community members' exposure to radioactive material released from the site from 1951 through 1988.

Both reports are part of the Fernald Risk Assessment Project, which is being conducted to estimate human health risk for the community surrounding the former FMPC resulting from exposures to radioactive material released from the site during its years of operation.

PUBLIC REVIEW REQUESTED

We are asking for public review and comment on the draft Phase II Fernald Risk Assessment Report. Your review and comment will help us ensure that we have captured and addressed community health concerns and questions--in the results provided in the report and also in our planning for future work at the FMPC site. All public and scientific review and comment will be considered in the final version of this Phase II Fernald Risk Assessment Report.

The public review and comment period is 30 days. All comments are due by July 23, 1999. We will take your comments in any form - in writing (by mail, facsimile or electronic mail) or by telephone.

All public comment should be directed to:

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A copy of the Phase II Report, this summary and all accompanying fact sheets will be available soon on the CDC's Radiation Studies web site:

www.cdc.gov/nceh/programs/radiation

QUESTIONS AND ANSWERS, CONT'D

WHY ARE YOU FOCUSED SO MUCH ON URANIUM? WHAT ABOUT ALL THE RADON YOU TALKED ABOUT IN THE LAST REPORT?

Breathing radon gas and radon decay products emitted from the K-65 silos contributes very little to the radiation doses received by organs other than the lung. The risk of lung cancer death associated with FMPC-related radon exposure was evaluated in Phase I (the final Phase I Report was released in December 1998). For these other organs, uranium, thorium, and other radionuclides released from the FMPC between 1951 through 1988 are primarily responsible for radiation dose. As a result, this second phase of the risk assessment project focuses on the potential health effects that may result from exposure to radionuclides other than radon, primarily uranium, released from the FMPC site during its operating years.

WHAT ABOUT THE WORKERS' EXPOSURES? SHOULDN'T THEIR WORK EXPOSURE COMBINED WITH THEIR EXPOSURE FROM JUST LIVING NEAR THE PLANT INCREASE THEIR RISK?

Our report did not consider radiation exposures workers may have received on the job. We are working with CDC's National Institute of Occupational Safety and Health (NIOSH) to understand the implications of this risk estimation for workers.

IN RELATION TO THIS REPORT, WHAT SHOULD I DISCUSS WITH MY DOCTOR?

If you have concerns about any of the cancers evaluated in this report, you should discuss those concerns with your health care provider. Your health care provider can also answer your questions regarding the signs and symptoms of these cancers. CDC is currently working with the Fernald Health Effects Subcommittee, ATSDR to inform area physicians about the health research the public health agencies are conducting in the Fernald area. In addition, you may find it very helpful to provide a copy of this report or this Summary of Results to your health care provider. CDC is working to post general information on each cancer listed in this report on our web site at www.cdc.gov/nceh/programs/radiation.

CAN I GET ANY TYPE OF MEDICAL SCREENING TO CHECK IF I HAVE THESE CANCERS?

Currently, no government or professional organizations recommend any existing medical technology for routine use to screen for leukemia, kidney cancer or bone cancer in persons without symptoms. Breast cancer screening is recommended by a number of national and professional organizations; however, there is no need for women in this area to receive a mammogram more frequently than is already recommended because of their Fernald-related radiation exposures. Currently, the Department of Health and Human Services' Preventive Services Task Force recommends that women aged 50-69 be screened for breast cancer every 1-2 years with mammography alone or mammography and a yearly clinical breast exam. Because experts do not agree on the use of routine screening mammography and clinical breast exams in women aged 40-49 or 70 and older, these women should consult with their primary health care provider about breast cancer screening. CDC already funds the state of Ohio through its National Breast and Cervical Cancer Control Program to provide free screening mammography to women who cannot otherwise afford it. To learn more about this program, you can call (513)584-4342 or (888) PAP-MAMM.

Key Points

- Risk estimation is not an exact science.
- With current available science, we cannot prove or disprove that an individual's cancer was caused by exposure to radioactive materials released by the former FMPC during its production years.
- We did not collect data from community members; therefore, we had to make assumptions regarding such things as exposure history and lifestyle factors that may have affected dose.
- Estimates of population size, maximum dose and lifetime risk are based on mathematical models.
- This risk assessment includes only exposures resulting from releases of radioactive materials from the FMPC during its years of operation, 1951-1988.
- This risk assessment includes only exposures to residents in the surrounding community (within 6.2 miles of the center of the FMPC site). No exposures incurred as a result of working at the FMPC are included.
- This risk assessment includes exposures resulting from inhalation, ingestion and direct external exposures to radon, uranium and thorium isotopes and their decay products and other radionuclides released from the FMPC from 1951 through 1988.
- Because components of this risk assessment process are uncertain, all resulting estimates are uncertain.

Public involvement is critical to this project and for all of CDC's public health activities in the community surrounding the FMPC.

CDC and the Agency for Toxic Substances and Disease Registry will continue to work closely with this community to better understand the health effects of Fernald and to ensure the community has this information in order to make informed decisions on personal health care as well as community action decisions.

We encourage your input through attendance at the quarterly meetings of the Fernald Health Effects Subcommittee, public meetings and through telephone calls. The Fernald Health Effects Subcommittee advises CDC and the Agency for Toxic Substances and Disease Registry on the community's perspective of the type of health activities that are needed for the Fernald workers and community. Subcommittee meetings also provide a forum for community members to share their concerns with subcommittee and agency representatives.

Each year, CDC develops a research agenda that provides the framework for funding new projects. Advice obtained from FHES is taken into account in the development of this agenda and the funding of the new work. Public meetings are held quarterly in the local area near the FMPC site and are announced through public notices in local newspapers, in community calendars and through CDC's Fernald mailing list.

The Fernald Health Effects Subcommittee

The National Institute for Occupational Safety and Health (NIOSH) is the sponsoring agency for the Fernald Health Effects Subcommittee. To get on the mailing list for Fernald Health Effect Subcommittee activities, contact the executive secretary for this committee (address and/or phone number below).

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