PCTC

PAVEMENT COATINGS TECHNOLOGY COUNCIL

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Pavement Coatings Technology Council

Comments on

Protocol: Assessment of Occupational Exposure to PAHs in Coal Tar Sealant Applications. Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

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GENERAL COMMENTS

1. PCTC believes that NIOSH's proposed study of occupational exposures related to sealant application will be important for the sealant industry, and requests that NIOSH consider PCTC a willing resource to draw on for information and assistance, including assistance in identifying and selecting companies and recruiting participants. To further PCTC's commitment to partnering with NIOSH on ensuring that the study produces scientifically valid and supportable data and conclusions, PCTC also requests that NIOSH consider establishing a scientific advisory committee, with representatives from NIOSH, technical experts, and from industry (PCTC members). The mandate of the committee would be to work through technical issues that may arise both in developing the study protocol and during the course of the study. As the study is envisioned to extend for several years, annual research meetings could be held to inform NIOSH and industry oversight personnel as well as to facilitate mid-course corrections, if needed. Whatever format future interactions between NIOSH and industry take, PCTC is available to meet with NIOSH at your convenience to discuss any or all of the topics raised in the attached comments.

2. The substance to be tested should be better defined and accurately described throughout the protocol. In the Introduction and throughout the protocol, the substance is described as "coal tar-based pavement sealants" (CTS). This is incomplete and imprecise. Pavement sealants are manufactured using "Refined [Metallurgical[1]] Coal Tar Grade RT-12" (RT-12) meeting ASTM D490 – 92 (2011) standards. The refining process description and classification of RT-12 are fully described in ACCCI (1994). The process of making RT-12, the base material for refined coal tar-based pavement sealants (RTS) is described in ASTM D490-92. The protocol should adopt the designation for sealant used by the industry – RTS – rather than the less precise and potentially misleading CTS. The sealant is an emulsion manufactured and applied according to ASTM standards. In addition to ASTM D490-92, relevant standards are:
    - D5727 -00 (Reapproved 2011) – Standard Specification for Emulsified Refined Coal Tar (Mineral Colloid Type)

[1] To distinguish the coal tar produced in coking ovens from that found at legacy manufactured gas plant (MGP) sites, the term "metallurgical coal tar" is used by some researchers. The term reflects the fact that coking plant coal tar is derived from metallurgical grade coal to make metallurgical coke and, as a byproduct, metallurgical grade coal tar (e.g., Diez et al., 2002). One result is that the physicochemical properties of metallurgical coal tar are relatively consistent in tars derived from different coking ovens, and the crude coal tar can be consistently refined into many useful fractions/products. In contrast, MGP coal tars were derived from many different grades of coal, resulting in coal tars with unpredictably different physicochemical properties, even in single MGP locations where different grades of coal and perhaps different gasification processes were used at different times (e.g., Brown et al., 2006).

- D4866-88 (Reapproved 2011) – Standard Performance Specification for Coal Tar Pitch Emulsion Pavement Sealer Mix Formulations Containing Mineral Aggregates and Optional Polymeric Admixtures
    - Specification for D5727 sealer after the addition of aggregates and/or polymers.
- D6945-03 (Reapproved 2011) – Standard Specification for Emulsified Refined Coal-Tar (Ready to Use, Commercial Grade)
    - Ready to use D5727 sealer for commercial applications.
- D6946-13 (Reapproved 2013) – Standard Specification for Emulsified Refined Coal-Tar (Driveway Sealer, Ready to Use, Primary Residential Grade)
    - Higher water content.
- D3423-84 (Reapproved 2011) – Standard Practice for Application of Emulsified Coal-Tar Pitch (Mineral Colloid Type)

3. The protocol is more outline than study protocol. It is deficient in details for most aspects of the study. Much of what is lacking may be required by an Institutional Review Board (IRB) in their review of the draft protocol. Activities described overs years 1 and 2 of the study include "refinement" of the protocol, which suggests that the draft protocol under review may not be intended to describe a Good Laboratory Practices (GLP) study or a study compliant with EPA Office of Chemical Safety and Pollution Prevention (OCSPP) Series 875 guidance, which would involve an approved, signed protocol with procedures described for making protocol amendments as well as detailed methodologies described for each step of the study. Protocols are desirable to promote successful replication of studies and also assist in peer review. Protocols assist in thinking through the details of a study, including safety precautions, lists of required equipment, sampling procedures, chains of custody, analytical methods, sample archiving, QA and QC measures, calculating and reporting results, and predefining and documenting criteria for including or excluding data to avoid bias. In addition to NIOSH study guidelines, additional sources of guidance for planning exposure studies that meet regulatory requirements include OCSPP Series 875 Guidelines (EPA, 2015) and, more generally, the Organization for Economic Cooperation and Development (OECD, 2015).

   It seems likely that the proposed study will be considered in future regulatory deliberations concerning RTS. To enhance its usefulness, PCTC suggests that the study protocol undergo further development so that the study is conducted in accordance with regulatory requirements.

4. The protocol does not include a description of quality assurance (QA) or quality control (QC) measures for any - field or laboratory or data management or data interpretation or etc. – aspect of the study. Is QA/QC a part of the program? Have all methods been validated for the purposes described, with approved Standard Operating Procedures

(SOPs)? Is an SOP already in place for protocol amendments? If there is a separate QA plan, can it be made available for review? When NTP undertakes a new research program (such as the PAH mixtures project), it typically seeks review and approval by its Board of Scientific Counselors (BSC). Does NIOSH have a similar internal review board that has or will review this project? As the project involves "influential" or "highly influential" science, as defined by the Office of Management and Budget (OMB), will the protocol be subject to any review procedure specified for influential or highly influential projects?

5. The study timeline as proposed in the outline is unworkable. NIOSH appears to have afforded ample time (2 years) to draft a protocol, set up study logistics, obtain IRB approval and complete of several pilot studies. However, as laid out in the outline, the plan calls for all of this to occur in year one (2015) - at least for pilot work. This seems to be an overly ambitious schedule, especially if the version of the protocol available for public comment is the most current version. The remainder of the timeline is devoted to refinement of study design, recruitment and field survey activity but no time seems to be allotted for review of protocol amendments or for additional IRB review, which may be needed if the study design changes as a result of pilot findings. Alternatively, NIOSH may wish to consider dividing the study into two parts, each governed by its own protocol: an initial pilot study, to be followed by development of a full study protocol. This approach may have the advantage of more clearly defining the elements of each protocol while reducing the need for extensive protocol amendments that could result in delays.

6. Analytical methods proposed for blood and urine include measurements of PAH DNA adducts. PAH DNA adducts are known markers of PAH exposure, but whether adducts are related to effects is less certain. Further, PAHs are ubiquitous, and like all humans, sealant applicators are exposed to PAHs from many different sources. The protocol mentions a method of identifying exposure to cigarette smoke, but the protocol should provide additional information about how possible co-exposures to PAH-containing materials (such as in the diet, or routine proximity to other sources of PAHs) will be taken into account.

7. With regard to dermal sampling, the literature cited in the study outline states that, in occupational settings, dermal exposure to PAH-containing mixtures can exceed inhalation exposures. Techniques for dermal sampling (Skin/Wipe/Hand Wash) in this study are not provided in the protocol and there is no discussion of how methods for dermal sampling will be selected. Furthermore, there is no discussion of how (or if) dermal sampling methods will be validated and calibrated. Because this information is not usually included in the reports of findings with various dermal sampling methods, validation and calibration would be a crucial part of the study design, and would help

bring the protocol closer to a guideline study. Proper validation and calibration must include not only a QC demonstration of analyte recoveries from spiked collection medium, but also absorption efficiency of the medium from spiked skin surrogate surfaces.

8. Non-invasive observational sampling in worker studies is challenging. Adding invasive sampling (blood and urine collection) increases the challenge as well the logistical demands of many testing locations. This study is an outdoor study and will be subject to weather interruptions since pavement sealing cannot be done in the rain or on wet surfaces. Given the expectation that the number of application crew workers will be small (3-6) and the goal of sampling 200 worker-days, testing at many sites will be required to reach the minimum number of monitoring events for a valid (i.e., ethical) study. How will these circumstances be addressed in the protocol?

9. PCTC suspects that funding for this study is being provided by NIEHS/NTP as part of their "real world" PAH-containing mixtures project. This project, in turn, is funded by EPA at the behest of EPA's Science Advisory Board (SAB). If this is not, in fact, the program funding the study, the protocol should indicate which program is funding the study and how the study advances the goals of that program. On the assumption that the "real world" PAH-containing mixtures project is the source of funding, the protocol should improve the explanation of how the proposed project fits into the program. The intent of the mixtures project, as envisioned by the SAB, is to inform and ultimately replace EPA's Relative Potency Factor (RPF) approach to assessing risks potentially associated with PAH-containing mixtures for the reason that the SAB found that the scientific basis for the RPF approach is weak, and results in inaccurate estimations of risk (USEPA SAB, 2011). NTP's BSC approved the PAH project as a way to "move the whole field of mixture science forward" (NIEHS Environmental Factor, 2013). The protocol does not address how the analytical program proposed in the NIOSH protocol advances "mixture science" as the analytical procedures described appear to focus on individual PAHs without explaining how exposure to RTS may differ from exposures to individual PAHs (which does not happen in the real world) or exposures to other PAH-containing mixtures.

SPECIFIC COMMENTS

INTRODUCTION

p. 2, 1st paragraph in introduction:

Comment: This paragraph provides an incomplete description of the cancer hazard classification of coal tar and coal tar products. The cancer classification of coal tar is based on crude (i.e., unrefined) coal tar rather than refined metallurgical

grade coal tar. With the exception of the U.S. Food and Drug Administration (FDA), which classifies coal tar and derivatives as "Generally regarded as safe and effective…," reviews of the hazard classification of coal tar in the past have relied primarily on non-pharmaceutical anecdotal and case reports, including citations that have been found to have little or no relevance to exposure to refined coal tar (e.g., IARC). While regulated entities may be required to comply with standards based on scientifically unsupported classifications, scientific research must be based on first-hand understanding of the science, not on outdated reviews of committees that have failed to accurately consider all of the available evidence. Hazard classifications of coal tar based on systematic reviews, such as that recently promulgated by Work Safe BC (Spinelli et al., 2012), can be expected to come to different conclusions than outdated IARC or NTP reviews. A more complete description of hazards potentially posed by exposure to coal tar and fractional distillates of coal tar is as follows:

- Coal tar and fractional distillates of coal tar are specifically designated "Generally Recognized as Safe and Effective" in FDA regulations (CFR 21§358) for use in over-the-counter skin medications. Coal tar pharmaceuticals have been used for more than a century, and there are many epidemiological and clinical studies available of patients who have applied large amounts of coal tar medications directly on their skin.
- FDA's Cosmetic Ingredient Review (2008) process has, however, found that the data are insufficient to approve use of coal tar in cosmetics, so today you won't find the coal tar eye liner that was used in the distant past.
- There is no evidence that low level or intermittent exposure to refined coal tar or coal tar pitch has caused cancer in humans. This category describes occupational and other exposures to RTS (Spinelli et al., 2012).
- There is little evidence that high level, repeated exposures has caused cancer in humans. This evidence consists largely of reports from the past, such as chimney sweeps exposed to PAH-containing materials (possibly including non-metallurgical grade coal tar) in London in the 18th century (but not chimney sweeps in other countries at about the same time) and late 19th – early 20th century factories, at a time when industrial hygiene practices were virtually non-existent. The working conditions described in these reports include exposures to many chemicals in addition to coke and coal tar (Spinelli et al., 2012).
- There are some studies conducted in modern factories with high temperature (thousands of degrees Fahrenheit) industrial processes such as aluminum smelting or coke oven gases that show some adverse effects (Spinelli et al., 2012).

p. 2, 2nd paragraph in introduction: "CTS are generally less expensive [than asphalt-based sealants]…."

Comment: A price comparison is neither relevant nor appropriate in this study protocol. Regardless, the statement is historically incorrect. In choosing which

sealer to use, up-front costs are not the only factor considered by most customers. Life cycle costs are generally more important. RTS are considered more desirable because of fuel resistance, durability, color retention, and consistency (i.e., can be manufactured to a performance-based standard). Asphalts are variable when emulsifying because of differences in chemistry from crude source to crude source and refining methods used.

p. 3, 2nd paragraph: "Discussion with USGS investigators indicated that the post-application- airborne environmental concentrations of PAHs can vary widely, as can the concentration of PAHs in the product material being applied to the pavement."

Comment: PCTC does not view USGS as impartial observers/scientists when it comes to RTS. Over the years, USGS has repeatedly showed its hand – it wants RTS banned and has gone to great lengths to further its agenda against RTS and the members of PCTC. While it is understandable that NIOSH would not wish to put itself in the middle of PCTC's ongoing dispute and litigation with USGS concerning the scientific integrity of the USGS studies, it is disappointing that, on the one hand, NIOSH did not approach industry with requests for information, while on the other felt unconstrained to consult with the "USGS investigators" who, in their decade of "research" targeted at coal tar, have gone out of their way to avoid consultations with industry. Unfortunately, this oversight on the part of the USGS has heightened the mistrust of government agencies by sealcoating companies, including some that have reviewed NIOSH's draft protocol.

p. 3, 2nd paragraph: "Review of the literature indicates that some very limited measurements have been made of occupational airborne levels of PAHs during coal tar chip sealing, a roadbuilding process which currently uses an asphalt-based binder, but which historically did use a coal tar-based binder in some locations [11]. No occupational airborne levels of PAHs associated with application of CTS to blacktop parking lot pavement have been found in the literature.**"**

Comment: A well-conducted exposure study of sealcoat applicators and related occupational exposures has been conducted (Juba, 1991), is readily available both on PCTC's web site and on request, and has been made available to NIOSH. The coal tar chip seal literature is irrelevant, as coal tar chip seals have not been done in about four decades and the process is not similar to sealcoating. Chip seals were distributor truck spraying refined tar (not necessarily grade RT-12) at about 0.25 to 0.50 gallons per square yard followed by an application of washed and graded aggregate, which was then rolled with pneumatic rollers. The refined tar was typically sprayed at 325° F. In contrast, RTS is a clay-stabilized, water based emulsion handled and applied at ambient temperatures.

p. 3, 4th paragraph: "1-HP measured in urine is the biomarker identified as the recommended biological exposure index (BEI) for PAHs by the American Conference of Governmental Industrial Hygienists [ACGIH]."

Comment: The use of urinary 1-HP may be problematic: the ACGIH adopted a non-quantitative BEI for PAHs using 1-HP for lack of sufficient supporting data. How much is known concerning the pharmacokinetics of 1-HP metabolism, e.g. urinary half-life of both pyrene and 1-HP? Such supporting data should be cited here.

p. 3, last paragraph: "Micronuclei are small, round to oval shaped deoxyribonucleic acid (DNA)-containing structures found in blood that originate from chromosome fragments or from the loss of whole chromosomes. Elevated micronuclei frequency in blood will be used as a biomarker of effect potentially related to PAH exposure since this measure has been identified as a surrogate marker of defects in DNA repair and chromosome segregation**.** Two large international collaborative studies have shown that increased lymphocyte levels of micronuclei predict a higher incidence of cancers several years later [15, 16].**"**

Comment: Is it the case that the "two large…studies" have indicated that the observed effect is only related to exposure to RTS? If not, how will the effects related to exposures to other materials be quantified and distinguished from effects, if any, related to exposure to RTS? How will these other exposures be explained to the human volunteers? How will these integrated exposure risks be deconflated and reported in the literature? How will the integrated exposure risk be described in relation to occupational, non-occupational, and/or ambient exposures to the presumably many products that may influence micronuclei frequency? Will there be an effort made to link these integrated, general indicators of effect to RTS only? What is the rationale for including an integrated, general indicator of effect in a study of exposure related to a single, specific product?

p. 4, 2nd paragraph:

Comment: As noted by Talaska et al. (2014; ref. 17), PAH DNA adducts are well known markers of exposure, but are of uncertain relevance as markers of effect. How will this be explained to volunteers? Especially in light of the inclusion of non-RTS, non-PAH, non-coal tar specific, integrated markers of effect measurements described in the micronuclei paragraph, above?

Study Rationale:

p. 4, entire section:

Comment: PCTC suspects that funding for this study is related to the suggestion made by EPA's SAB that EPA make funds available to NIEHS/NTP to conduct toxicological studies of a selection of PAH-containing mixtures to inform, with a view to ultimately replacing, EPA's inadequate Relative Potency Factor (RPF) approach to assessing PAH risks (EPA SAB 2011). If this is the case, the discussion of NTP Report on Carcinogen (RoC) listings of individual PAHs is not a complete study rationale. A rationale that included discussion of exposure to the mixture that is RTS in contrast to individual PAHs would be appropriate Fair or unfair, using the advocacy research of the USGS as a study rationale will unquestionably raise the level of distrust among potential industry participants. NIOSH should consider inviting PCTC to give a seminar on White Hat Bias in the Environmental Sciences.

Study Objective:

p. 4, 1st Study Objective paragraph: "The study will be, to the best of our knowledge, the first occupational exposure assessment for PAHs among these workers.**"**

Comment: See Juba (1991). Also, if PCTC is correct in assuming that the source of funding is the "real world PAH-containing mixtures" project, it would be appropriate to include some assessment of exposure to the mixture contrasted with exposure to individual PAHs.

p. 4, 1st Study Objective paragraph: "….higher PAH-content material)…**"**

Comment: What would that material be? How would it be relevant to a study of RTS?

p. 4, 1st Study Objective paragraph: "….3) to assess biomarkers of effect potentially related to PAH exposure in blood (micronuclei frequency)"

Comment: See previous comment on micronuclei studies. How would finding excess micronuclei be relevant to a study of RTS exposure? How would a control group be selected? How would potential micronuclei-increasing exposures in the control group be controlled or accounted for?

p. 4, 1st Study Objective paragraph: "…5) to assess dermal exposure levels to PAHs…"

Comment: By what method? No information is presented.

METHODS

Identifying and Selecting Companies and Survey Sites:

p. 5, entire identification and selection section.

Comment: NIOSH needs to understand that the sealcoating industry perceives that it has been subjected to unfair, unwarranted attack by employees of the US Government (specifically the USGS) acting as advocates rather than as scientists. Sealants based on refined tar have borne the brunt, but industry personnel have witnessed government employees stating bluntly that, once they get rid of coal tar, asphalt is next. With awareness of the situation, NIOSH needs to be prepared to address the following questions that may be raised by prospective companies:

- Why would a company volunteer to participate in this study conducted by a government that is trying to put it out of business?
- While individual participants will receive nominal payments, participation in this project will add costs to the company that may be significant. Costs could include time, coordination, interruptions and employee discomfort. How can these be minimized?
- Will split samples be made available to PCTC or the participating company or an agreed upon representative if requested?
- Will there be a system in place to independently verify samples, results, QA/QC and related issues?
- Why does the protocol not include the well-known (within the industry) Juba (1991) study? (this is easily addressed by revising the protocol to take the Juba study into account)
- Why does the study focus on applicators and not also include sealcoat emulsion manufacturers?

Recruitment and Selection of Participants:

p. 5, entire recruitment section: "The employer's workers involved in these jobs will be contacted and a study consent form will be reviewed with them. Questions will be addressed by the NIOSH representative *at that time*. The NIOSH representative will obtain consent of the workers who agree to participate in the exposure monitoring study."

Comment: Addressing questions "at that time" may not be approved by an IRB, as it gives the prospective subjects no time to review the consent form prior to signing. PCTC recommends a first visit to each prospective company to meet with the prospective subjects and explain the study and consent form. Each would receive a copy of the form at this time. After a suitable interval (>7 days), but before the actual test begins, a second visit would obtain informed consent from willing volunteers. Consent forms would be made available in English and any other language required for understanding by the subject. Follow 40 CFR 26.

Field Surveys:

p. 6, 1st paragraph: "A total of 14 field surveys are planned for this study, resulting in approximately 200 worker-days sampled. Each survey will include repeated sampling of a crew of workers over a period of several days. A minimum of 12 worker-days will be required to conduct a survey (e.g. 3 sampled workers over a period of 4 consecutive days). NIOSH will arrange with the company, and other relevant parties, to conduct exposure monitoring at the job site(s) for the duration of each survey. Depending on the size of the contracted work, it may be necessary to follow a company to more than one site to achieve the minimum of 12 worker-days sampled during a survey. The first two field surveys will serve as a pilot studies to observe worker tasks, to identify potential exposure hazards by source and route, to evaluate sampling strategies, and to compare and test methods of analysis (see Pilot Survey Additions). Any adjustments to the protocol (e.g. study methods, sampling strategies, analytical methods, agents of interest, etc.) will be addressed during this period."

Comment: Not addressed here is validation of sampling and sample-handling methods under proposed field conditions. PCTC recommends the performance of a field recovery pre-field evaluation under worst-case conditions (e.g., weather, expected loading of matrices) prior to actual field testing with subjects.

p. 6, 2nd paragraph: "As described below, NIOSH will conduct: 1) air monitoring, 2) urine monitoring, 3) dermal monitoring (skin wipe/hand wash), and 4) and blood monitoring. All samples will be shipped or carried to the laboratories for analysis following standard procedures."

Comment: Again, no information on experimental methods or materials is included. These should be defined and verified as acceptable for the study before actual testing.

p. 6, 2nd paragraph: "…and obtaining hand wipe samples…"

Comment: As manufacturers of RTS, PCTC members recommend that applicators wear gloves as part of their personal protective equipment when handling RTS. Is the goal of hand wipe sampling to measure the effectiveness of different types of gloves?

<u>Air Sampling</u>

p. 7, 1st paragraph: "This method includes personal sampling for particulates as well as volatiles and semi-volatiles on OVS-7 …"

Comment: OVS tubes are very small in resin mass, which could result in breakthrough. The residue retention of and recovery efficiency from such tubes

used as described must be verified as acceptable for the study prior to field testing.

Urine

p. 7, 1st "Urine" sentence: "Two urine samples (one pre-shift and one end-shift) will be collected per worker on each workday."

Comment: Does the metabolism of PAHs to these metabolites support such short collection durations?

p. 8, 4th paragraph: "Measurements will be performed with the Vitros Autoanalyzer (Ortho Clinical Diagnosis)."

Comment: Can this method be validated?

Pilot survey additions (urine):

p. 8, entire pilot survey section.

Comment: What will determine if the pilot surveys will trigger protocol amendments? Is there an SOP for amending the protocol? Is there documentation for the pilot survey methods? PAH DNA adducts are commonly observed markers of exposure. How will the difference between markers of exposure and markers of effect be explained to study volunteers?

Skin Wipe/Hand Wash

p. 11, 3rd paragraph: "Dermal wipe samples will be obtained and analyzed by the NIOSH contract laboratory to assess worker dermal exposure levels to PAHs and to aid in the interpretation of biological monitoring results….."

Comment: No method is described or cited for this procedure. The IRB may require verification of any such method for its a) safety for use on human subjects and b) residue removal efficiency from skin, for the adjustment of quantitative results. Cadaver skin testing with target PAHs would be strongly advised, to determine removal efficiency, if scientifically and ethically acceptable data are not currently available.

Blood

No comments at this time.

Bulk sampling of sealant material

p. 10, 1st paragraph: "In order to help interpret the exposure monitoring results, one bulk sample of sealant material will be collected, per survey, for analysis of PAH content by NIOSH using the same NIOSH analytical method(s) described in the air sampling

section above. Additional bulk samples may be obtained for NIOSH analysis if more than one lot of sealant product is used during a survey."

Comment: Once RTS manufacturers sell the product, it is no longer in their control. RTS manufacturers are aware that some sealant applicators modify sealant products in different ways, including mixing RTS with asphalt-based sealant, addition of solvents, and addition of other chemicals intended to speed curing times. To make the data collected by NIOSH interpretable, the "per survey" aspect of sealant material collection is imperative. In addition, each batch of sealant material should be characterized not just for PAH content, but for solvents, for compounds that may be typical of asphalt-based products (but not refined tar-based products) and possibly for other ingredients.

Exposure Determinants

No comments at this time.

Data Analysis

No comments at this time.

Study Time Line

p. 13, 2nd paragraph: "The first year will focus on protocol refinement and review, Institutional Review Board (IRB) approval, recruitment and contact with companies, observation of worker tasks, and two pilot field surveys. Protocol refinement will include selection of methods and sampling strategies best suited to assess occupational exposures, as determined by the results of the two pilot surveys. Recruitment may begin with local companies, followed by establishing industry contacts in a wider area."

Comment: Also focus on development and obtaining IRB approval of all subject recruiting and consent documents. NIOSH may wish to consider dividing the study into two parts, each governed by its own protocol: an initial pilot study, to be followed by development of a full study protocol. This approach may have the advantage of more clearly defining the elements of each protocol while reducing the need for extensive protocol amendments.

Data Management

p. 13, 4th paragraph: [entire section]

Comment: Photographs of monitored activities are not mentioned. If they are made, all appropriate guidelines for de-identification must be followed. In light of recent breaches of digital information, it may be that paper files (properly cared for) are more secure than electronic files.

Risks and Benefits for Study Participants

No comments at this time.

Emergency care

No comments at this time.

Notifying Participants of Individual Results

No comments at this time.

Summary of Results to Participating Companies and Labor Unions

No comments at this time.

AUTHORITY AND TRADE SECRET PROTECTION

No comments at this time.

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Acronyms & Abbreviations

ACCCI	American Coke and Coal Chemicals Institute
ACGIH	American Conference of Governmental Industrial Hygienists
ASTM	American Society for Testing Materials
BEI	biological exposure index
BSC	Board of Scientific Counselors
CDC	Center for Disease Control and Prevention
CFR	Code of Federal Regulations
CTS	coal tar-based pavement sealants
DNA	deoxyribonucleic acid
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food & Drug Administration
GLP	Good Laboratory Practices
IRB	Institutional Review Board
MGP	manufactured gas plant
NIEHS	National Institute of Environmental Health Science (a division of the National Institutes of Health)
NIOSH	National Institute for Occupational Safety and Health (a division of CDC)
NTP	National Toxicology Program (a division of NIEHS)
OCSPP	EPA's Office of Chemical Safety and Pollution Prevention
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
PAH(s)	polycyclic aromatic hydrocarbon(s)
PCTC	Pavement Coatings Technology Council
PPE	Personal Protective Equipment
QA	quality assurance
QC	quality control
RPF	Relative Potency Factor
RT-12	Refined [Metallurgical] Coal Tar Grade RT-12
RTS	refined coal tar-based pavement sealant
SAB	Science Advisory Board
SOP	Standard Operating Procedure
USGS	U.S. Geological Survey