

August 21, 2000

The Honorable Carol Browner  
Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Building  
Room 3000, #1101-A  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460

Dear Administrator Browner:

The following comments are submitted on behalf of People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, Physicians Committee for Responsible Medicine, and Earth Island Institute. These animal protection and environmental organizations have a combined membership of more than nine million Americans concerned with the suffering of animals used in laboratories.

#### **GENERAL COMMENTS**

The Environmental Protection Agency (EPA) letter to HPV chemical testing participants dated October 14, 1999 (based upon a negotiated agreement between the EPA, industry, the Environmental Defense Fund, and animal protection representatives) states in part:

“1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is significant data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

8. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.”

We are therefore deeply concerned that the first two test plans submitted, for petroleum coke and aminosilanes, have ignored these instructions to a significant degree. The agglomeration of individual substances into categories is an important issue. The boundaries of any category are, to a large degree, arbitrary and dependent on the specific information and values that decision-makers in industry and government consider in moving forward. This variability exacerbates the animal protection community's concern that animals will suffer and die in HPV chemical tests that could easily have been avoided. When a reduction in the use of animals is not a primary focus of the



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AN INTERNATIONAL  
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THE RIGHTS OF ALL ANIMALS

entire program (as it clearly is not), industries and/or companies will base their submitted categories on their own specific experiences. For example, the American Petroleum Institute (API) has submitted petroleum coke without considering coal coke, or even other carbon-based solid organic mixtures that might be created by or used in the tire and rubber, plastics, steel, utility, or gold-mining industries.

If the EPA's commitment to reducing the use of animals in the HPV program is to be more than lip service, cross-industry fertilization is essential in creating an efficient program. Because each industry will want to optimize tests for its specific product, there is little incentive for creating coherent test plans across industries. This fact clearly demonstrates a major flaw of the HPV program. The responsibility for being proactive in this arena lies with both industry and with the EPA – the agency that created the HPV program, that demanded massive numbers of animal tests, and that must ensure adherence to the principles set forth in the October 14, 1999, agreement. We are asking for a response from the EPA, as well as from API and the Silicones Environmental Health and Safety Council, regarding how they plan to enhance inter-industrial approaches to minimize overall testing and limit the number of animals killed in this program.

A careful analysis of the first two categories further reveals that the testing proposed will not serve any effective purpose in protecting the public or the environment but merely serves to “check the box” – an approach specifically ruled out by the October 14, 1999, agreement. Our specific comments on the first two submitted HPV test plans are attached and, in addition to the response requested above, we also look forward to a specific response to each of these concerns. I can be reached at (757) 622-7382, ext. 304, by e-mail at [jessicas@peta-online.org](mailto:jessicas@peta-online.org). Correspondence should be sent to my attention at the following address: 4800 Baseline Road, #E104-390, Boulder, CO 80305.

Sincerely,

Jessica T. Sandler  
Federal Agency Liaison

cc: The Honorable Robert C. Smith  
The Honorable F. James Sensenbrenner, Jr.  
The Honorable Ken Calvert  
The Honorable Jerry F. Costello  
Council on Environmental Quality

## Comments on the Petroleum Coke Grouping and Test Plan

The two substances listed for grouping in the petroleum coke test plan are petroleum coke (“green coke”) and calcined petroleum coke. Both of these products are solid, nearly pure carbon products resulting from petroleum processing and refining. The primary difference between the two products is that calcined petroleum coke is simply green coke that undergoes a secondary processing step to remove the few hydrocarbons that remain in the raw product.

### Comments on the Grouping of Petroleum Coke

Chemically, petroleum coke and calcined petroleum coke are very similar. They are almost pure carbon (> 90 %), with trace amounts of hydrocarbons trapped into their structure. It is quite sensible that these two substances are grouped. However, the composition of petroleum coke is also quite similar to many other commonly used industrial materials, some of which are included on the list of HPV substances. These compounds are essentially highly polymerized carbon, with a minimal amount of associated hydrocarbons. Specifically:

- Coal, anthracite, calcined (CAS #68187597)
- Coke, (coal) (CAS #65996772)

are appropriate to include in the petroleum coke group, to create a larger coke group. These two substances are also essentially pure carbon, with minor amounts of other hydrocarbons present. Other commonly used industrial substances that may have data applicable to the petroleum coke group include carbon black, uncalcined anthracite coal, other coal, activated carbon, charcoal, thermal black, and graphite. All these compounds are characterized by high carbon contents (> 90%), low hydrocarbon content, low aqueous solubility, and they all have generally low levels of commonly identified toxic compounds.

While the petroleum coke group provides a starting point for using a smaller set of tests to characterize a larger set of compounds, the short list of compounds in the group demonstrates the problem of a single industry sponsoring the grouping of compounds. Often, that industry may not include compounds from other industries that may be appropriate. In this case, API has not included compounds that are a product of coal mining that have extensive industrial uses in the steel industry. To minimize overall testing cost (both in dollars and in animal suffering), it is critical that cooperation among industries takes place to make the HPV chemical groupings inclusive of all specific compounds that are relevant to each group.

### Comments on the Petroleum Coke Test Plan

The Petroleum Coke Test Plan generally does a good job of using existing data, with the proposed tests being the testing for aquatic toxicity to daphnia and algae, terrestrial toxicity to earthworms, and reproductive/developmental effects. **We strongly disagree**

**that the reproductive/developmental test is necessary and appropriate, as petroleum coke is a well-characterized substance and abundant data exist on many analogous compounds.** All evidence indicates that these tests will not demonstrate any unique effect and any toxicity may simply be a result of low-level hydrocarbons in the coke that may affect results.

Previous toxicity testing (acute toxicity and repeat dose toxicity studies) shows that petroleum coke behaves simply as organic carbon, with no other side effects, which is not surprising, as petroleum coke is basically just carbon. In addition, there are extensive existing epidemiological and toxicological studies on workers dealing with petroleum coke and other analogous substances from petroleum coker facilities<sup>1</sup>, carbon black operations<sup>2,3</sup>, and coal coke dust<sup>4</sup>.

Toxicity from petroleum coke will be a function of two factors:

1. Toxicity due to the composition of bioavailable chemicals in the coke.
2. Toxicity due to the physical nature of fine coke particles.

For petroleum coke to pose a reproductive hazard, it must be absorbed and circulate in the body to affect reproductive organs. Previous studies show that petroleum coke behaves similarly to other fine grained dust particles and will not be physically absorbed. Therefore the physical characteristics of the dust would not be an issue in reproductive toxicity. The potential for chemical reproductive effects would simply be due to trace chemicals found in petroleum coke, especially the uncalcined version that may have a higher hydrocarbon content. Fortunately, there is already an extensive database on the chemical and toxicological profiles on the sorts of potentially toxic hydrocarbon compounds that would be found in the petroleum coke, including polyaromatic hydrocarbons<sup>1,5,6</sup>, and general petroleum compounds<sup>7</sup>.

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<sup>1</sup> Futagaki, S.K. "Petroleum Refinery Workers Exposed to PAHs at Fluid Catalytic Cracker, Coker, and Asphalt Processing Units," Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, Department of Health and Human Services, Cincinnati, OH. Publication No. 83-111, 1983.

<sup>2</sup> Robertson, J.M. "Epidemiologic Studies in North American Carbon Black Workers," *Inhalation Toxicology*, v. 8, Supplement, 1996, pp. 41-50

<sup>3</sup> "Chemical Hazard Information Profile Draft Report. Carbon Black, CAS No. 133-86-4," U.S. EPA, Office of Toxic Substances: Washington, D.C., 1981

<sup>4</sup> Lipscomb, J. and Lee, S. "Health Hazards Evaluation: Report No. HETA 81-421-1251." Port Arthur TX: Great Lakes Carbon Corp.

<sup>5</sup> Boulos, B.M. and A. Von Smolinski, "Risk Assessment of Potentiating Factors in Polycyclic Aromatic Hydrocarbons (PAH) Toxicity," in *Polycyclic Aromatic Hydrocarbons: A Decade of Progress, Proceedings of the Tenth International Symposium*, Battelle Press: Columbus, OH. 1981.

<sup>6</sup> Mumtaz, M.M. et. al., "ATSDR Evaluation of Health Effects of Chemical. Polycyclic Aromatic Hydrocarbons (PAHs): Understanding a Complex Problem," *Toxicology and Industrial Health*, v. 12 (6), 1996, pp. 742-984

<sup>7</sup> Sforzolini, G.S. et. al., "Environmental and Biological Monitoring of Mutagenic/Carcinogenic Hazards in Working Environments Exposed to Petroleum Derivatives," *Prog. Clin. Biol. Res.*, v. 207, 1986, p. 171-82.

We urge that before conducting any animal-based toxicity testing, API characterize the trace constituents of petroleum coke, to ensure that no known compounds with reproductive effects are present. If they are present, their concentration in the coke should be characterized and their potential toxic effect evaluated through risk assessment. In addition, the current workplace exposure data concerning petroleum coke and other carbonaceous substances can be used to further constrain the potential for reproductive health effects. This data, combined with existing toxicological data that show the relatively inert characteristics of the coke and similar carbonaceous substances, should be enough to demonstrate that no compounds with reproductive effects will be absorbed from petroleum coke, and that inhalation testing to evaluate potential reproductive and developmental effects is unnecessary.

Lastly, as an additional note, we question why tests for terrestrial toxicity have been included in this test plan. Point no. 4 of the October 14, 1999, letter specifically excludes terrestrial toxicity testing from the HPV Challenge program because the accompanying detailed environmental exposure assessments required by the OECD are not required in the HPV program. The SIDS protocol for toxicity to terrestrial organisms testing includes the OECD Test Guideline 207, which API states it plans to conduct.

## **Conclusions**

The petroleum coke group provides a good start for grouping several compounds and using existing data to minimize testing. However, the following issues need to be addressed:

1. The group is not broad enough, and should also include coal coke, and calcined anthracite coal.
2. The lack of other substances in the petroleum coke group points to an important flaw in the existing program, namely that cross-industry grouping is not being done. This will result in redundant testing.
3. Further chemical characterization of trace constituents in petroleum coke and application of existing toxicity testing, workplace exposure, and analog compound data are adequate to characterize the potential reproductive effects of petroleum coke. Additional testing for reproductive toxicity is unwarranted and unnecessary.