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U.S. Environmental Protection Agency
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PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

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Re: Comments on the API's Test Plan for the Heavy Fuel Oils Category

Dear Administrator Leavitt:

The following comments on the API's High Production Volume (HPV) test plan for the Heavy Fuel Oils category are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The API plans to conduct one combined repeat dose/reproductive/developmental test (OECD 422) on a sample of reformer residue and one combined reproductive/developmental test (OECD 421) on a residual fuel oil. Together, these tests will cause the suffering and death of yet another 1,300 animals in the HPV program. Despite the death toll these tests will cause, they are proposed even though only minimal characterization of the composition of these streams has been conducted and even though the tests are clearly unnecessary and duplicative of previously conducted testing on compositionally similar substances.

We have previously commented on similar plans submitted by the API, noting in particular the continuous nature of petroleum products (Petroleum coke, Lubricating oils, Waxes, Gasoline Category, Petroleum Naphthas, Petroleum Gas). The common theme in all these plans is that the primary toxicity of these complex chemical mixtures is generally due to either specific compounds that are already well-characterized (e.g., BTEX or PAH compounds), or to the overall physical properties of the mixture as oily materials. The toxicity of these sorts of materials has been extensively studied both through animal testing and human exposure studies.^{1,2,3,4} We have therefore disagreed with the proposed animal testing in all of the API's previous plans and this plan constitutes yet another clear check-the-box exercise which will add nothing to the already existing body of knowledge on heavy fuel oils.

We must once again repeat our concerns and cite several specific categories that have very similar composition based on compounds derived from this source material. The API's Crude Oil test plan lays out this argument quite well:

“There is a substantial body of data on products derived from crude oils, such as gasoline, diesel fuels, kerosene and jet fuels, lubricating oils and white oils, which

are subjects of other HPV test plans. Extrapolation from these studies provides insight into biologically active components of crude oils. Occurrence and severity of toxic effects appear correlated with concentration of polynuclear aromatic hydrocarbons (PAH) and PAH-containing nitrogen or sulfur heteroatoms (PAC). In addition there are significant data developed from monitoring effects of unintentional oil spills, providing 'real world' environmental information."

Heavy fuel oils share many of the chemical and physical properties of crude oils and the ACC's previous fuel oil categories. However, API fails to present any information beyond a cursory description of the chemical nature of these streams. Specifically, API provides no information on any of the PAH and heteroatom content of any of these streams, which are the most important determining factors for these streams' toxicity. A table summarizing the general composition of these different streams should be included in the tests plan, similar to Table 3 in the ACC's Fuel Oils test plan.

API has chosen not to identify the different products in this category based on the composition of the different category members. Rather they have identified them based on their operational analysis of the different places in which these products occur in the refining process – an arbitrary method that does not account for the actual product composition that controls product toxicity.

For example one atmospheric residual stream, [CAS #70592-79-9 Residues (petroleum), atm. tower, light] is described as consisting "of hydrocarbons having carbon numbers predominantly greater than C11 and boiling above approximately 200°C (392°F). This stream is likely to contain 5 wt % or more of 4- to 6-membered condensed ring aromatic hydrocarbons." In the different reformer residuals subcategory one stream [CAS# 64741-67-9, Residues (petroleum), catalytic reformer fractionator] is described as consisting "of predominantly aromatic hydrocarbons having carbon numbers predominantly in the range of C10 through C25 and boiling in the range of approximately 160 °C to 400°C (320°F to 725°F). This stream is likely to contain 5 wt. % or more of 4- or 6-membered condensed ring aromatic hydrocarbons," which is a similar description of the composition despite coming from different processes. Both of these compounds are also similar to the Pyrolysis Fuel Oil described in ACC's Fuel Oil Category as "consisting of C10+ and considerable PAHs."

Heavy Fuel Oils have many toxicological characteristics and contain the same toxic moieties as found in previously proposed categories of the Gas Oils, Lubricating Basestocks, Waxes, and Crude Oil categories proposed by API, and the Fuel Oils category proposed by the ACC Olefins panel. The ACC found that additional reproductive/ developmental testing of these compounds was unnecessary. These substances have all been thoroughly studied, are well-characterized including their reproductive and developmental effects, and there is an abundance of human exposure data on them as well. In short, a good understanding of the toxicity of these specific compounds and of similar mixtures containing these compounds already exists.

API has included an extensive body of existing data on essentially similar substances in its robust summaries and test plan. In particular, both pyrolysis fuel and atmospheric residual distilling streams have existing repeat dose, reproductive, and developmental data (e.g., pp. 54-68 of the heavy fuel oils robust summaries as well as the ACC fuel oils test plan).

The tests proposed in this plan are particularly unnecessary as the reformer residual sample apparently has a very similar composition to other streams in this test plan and others that have already been tested. The residual fuel oil sample is, as the test plan acknowledges, a mixture of all the other streams described in this plan. As all the other streams have extensive existing data on them and the results have shown an overall low toxicity of these streams, it is completely redundant to conduct further testing on these streams.

One has only to look at the API's Table 3, "Matrix of Available Data and Proposed Testing," (test plan, p. 30) to see the check-the-box nature of the API's proposed testing clearly. Of the eight refinery streams subcategories, a full seven are filled with "adequate existing data" for the repeat-dose toxicity endpoint and six are filled with "adequate existing data" for the reproductive/developmental toxicity endpoint. The remaining boxes will be checked with new animal testing even though reading across was satisfactory in other areas of this test plan.

We must ask the API, yet again, to undertake a thoughtful analysis of these materials and not condemn approximately 1,300 animals to suffering and death in order to retest well-characterized compounds whose risks are already well understood and quantifiable.

I can be reached at 757-622-7382, ext. 8001, or via e-mail at JessicaS@peta.org should you have any questions.

Sincerely,

Jessica Sandler
Federal Agency Liaison

¹ ATSDR. 1995. Toxicological Profile For Polycyclic Aromatic Hydrocarbons (PAHs). Prepared By Research Triangle Institute for the U.S. Department Of Health And Human Services. Public Health Service

² ATSDR. 1999. Toxicological Profile For Total Petroleum Hydrocarbons (TPH). Prepared by Research Triangle Institute for the U.S. Department Of Health And Human Services Public Health Service.

³ McKee, R.H. et al (1987b) Developmental toxicity of EDS recycle solvent and fuel oil. Toxicol 46, 205-215

⁴ IPCS/WHO (1982) Environmental Health criteria 20: Selected petroleum products. Geneva: World Health Organization.