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Subject Environmental Defense comments on the Heavy Fuel Oils Category

(Submitted via Internet 11/9/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Grayt@api.org)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the **Heavy Fuel Oils Category**.

The test plan and robust summaries for the heavy fuel oil (HFO) category were submitted by the American Petroleum Institute. This is an extraordinarily complex test plan, as the proposed category comprises 32 different CAS numbers broadly corresponding to different refinery streams produced from seven different processes. The sponsor states that the composition of the different streams varies widely and that it is difficult to present a representative detailed analysis for each of the streams. In general, the streams in the proposed HFO category contain high amounts of polynuclear aromatics and polycycloparaffins with relatively lower amounts paraffins and naphthenes. Several other related HPV substances have been submitted previously, including asphalt, fuel oil, jet fuel, kerosene and gas oils.

We commend the sponsor for preparing an informative and objective test plan and robust summaries. However, the category designation for the HFOs must be questioned, as the compositions of proposed members are quite different and their patterns of toxicities also are different. The sponsor uses a framework of seven subcategories for the HFOs, and we agree that those subcategories are appropriate for determining the need for new studies. We also agree with the sponsor's proposals regarding the conduct of additional tests for mammalian toxicity endpoints, but we do not agree that no additional ecotoxicity studies are warranted.

Specific comments are as follows:

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1. The NOAELs for the repeat dose studies vary from 3 mg/kg to >500 mg/kg. The dermal repeat dose study for the cracked residues indicates a wide array of hepatic and thymic toxicities at all doses tested, while several studies indicate that atmospheric residues have little or no toxicity at doses >500 mg/kg. The robust summary presents some compositional data for the cracked residues indicating that this fraction contains significant amounts of chemicals known to be toxic, such as benzopyrenes, benzantracenes, benzofluorenes and others. Does the sponsor also have good compositional data on the streams that possess low toxicity (such as the atmospheric residues) to compare with the cracked residues and other toxic streams? If so, comparisons of the composition data should be provided as it would be instructive for identifying the determinants of toxicity for the HFO streams and fractions.
2. The sponsor proposes to conduct a combined repeat dose/reproductive and developmental toxicity study on the reformer residue fraction and a reproductive/developmental study on residual fuel oil. The test plan also indicates that the test substances will be selected based on the potential for toxicity. This seems reasonable, but we do recommend that the specific criteria used to determine potential toxicity be provided in the test plan. We also note that the results of these additional studies combined with existing data on several other refinery stream subcategories should be sufficient to meet HPV requirements for the repeat dose, reproductive and developmental toxicity endpoints, regardless of whether or not the proposed category is accepted. But for the reasons stated above, designation of a single category for the refinery stream subcategories is not consistent with HPV criteria for category formation.
3. The sponsor proposes to conduct in vitro genotoxicity tests on several refinery stream subcategories and then to test for in vivo genotoxicity in cases where the in vitro results are positive. It is likely that many of the in vitro tests will be positive based on previous results and the knowledge that some of the streams contain significant amounts of known genotoxic chemicals. Therefore, we recommend that the sponsor conduct in vitro chromosomal aberration studies on the same five refinery stream subcategories evaluated using the Ames test.
4. Most of the ecotoxicity studies used residual fuel oil as the test substance, and the sponsor proposes to use these data for read across purposes for the other six refinery stream subcategories. This does not seem reasonable given the vast differences among the different subcategories. We recommend that additional studies be conducted for the three ecotoxicity endpoints using test substances for at least three of the other refinery stream subcategories selected on the basis of potential toxicity.
5. Existing data on individual chemicals and the refinery streams does seem adequate for all environmental fate endpoints.

Thank you for this opportunity to comment.

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