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DuPont Haskell Global Centers  
for Health and Environmental Sciences  
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August 31, 2010

**Via Federal Express**

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Attention: 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
1201 Constitution Ave., NW  
Washington, DC 20004

8EHQ-0810-18092A  
DCN:88100000417

Dear 8(e) Coordinator:



8 8 1 0 0 0 0 4 1 7

**Re: Draft TFE Multicenter Mortality Study  
Tetrafluoroethylene (CAS 116-14-3)  
Ammonium Perfluorooctanoate (CAS 3825-26-1)**

This submission reports on information contained in a draft report pertaining to an international collaborative epidemiology study of workers with potential occupational exposure to tetrafluoroethylene (TFE). The study also includes occupational exposure to ammonium perfluorooctanoate (APFO) as a potential confounder. The information in the draft report is still under review. With this submission, DuPont makes no representation with respect to the accuracy of the information in the draft report and this submission should not be construed to imply that DuPont agrees with the draft interpretations or statements contained therein. This information is submitted as it may meet EPA's criteria for reporting under TSCA §8(e).

The preliminary results are from an occupational cohort mortality study that has been conducted by third party investigators in Europe. Occupational exposure assessment for TFE and APFO are classified using a job history method developed by a different party in Europe. The study analyses include 7,015 workers with potential exposure to TFE at six facilities located in Germany, the Netherlands, Italy, Great Britain, and the United States (2 plants). The study principally reports standardized mortality ratios (SMR) as a statistical measure of association between mortality effects and exposure. The draft report is currently under revision with necessary corrections to the statistical methods identified by external advisors that will change the final analytic results.

In the preliminary draft report, the investigators present results from several analyses that indicate statistical associations with mortality from liver cancer and kidney and other urinary organ cancers and occupational TFE exposure. Statistical associations with these types of cancer are limited to certain definitions of potential TFE exposure such as duration of employment and categorical estimates of cumulative exposure (low, medium, or high) and are not consistently observed for all analyses of these specific outcomes. In the draft report the study investigators state that, "These findings can be considered only suggestive because of the small number of

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deaths [observed for these outcomes]." Additionally, statistical associations are reported for other mortality outcomes including esophageal cancer, pancreatic cancer, leukemia, and liver cirrhosis with TFE exposure. These results are also limited by small numbers of events and lack consistency with various exposure metrics.

Further, the draft report notes that most workers included in the study were also exposed to APFO such that APFO is considered a potential confounder for analyses of TFE exposure and mortality. In the draft report, the study investigators state that "...APFO was in general weakly or not related to liver and kidney cancer mortality", and that "...APFO did not confound relative risk estimates for TFE exposures (although it reduced their precision)." The investigators report preliminary results from several analyses that indicate statistical associations with esophageal cancer, kidney and other urinary organ cancers, leukemia, and liver cirrhosis associated with occupational APFO exposure. Again, these mortality results are limited to certain categorical definitions of potential cumulative APFO exposure (low, medium, or high), are limited by small numbers of events, and are not consistently observed for all analyses of these outcomes.

In summary, the preliminary draft report states that mortality results for liver cancer and kidney and other urinary organ cancers associated with TFE exposure can only be considered suggestive. At this time, the principal investigators are revising the draft report for final submission to the study sponsor. A copy of the final report will be submitted once it is available. It has been communicated to us that the principal investigators intend to submit a manuscript describing the final study results for publication in a peer-review journal by early 2011.

Sincerely,



A. Michael Kaplan, Ph.D.  
Director – Regulatory Affairs

AMK/JMS: clp  
(302) 366-5260

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