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October 2, 2006

FEDERAL EXPRESS

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Attn: Section 8(e)/FYI
U.S. Environmental Protection Agency
1201 Constitution Avenue, N.W.
Washington, D.C. 20004-3302

CONTAIN NO CBI

Re: Perfluorocotanoic Acid (PFOA)
Preliminary Partial Non-Occupational Blood Data

Dear 8(e) Coordinator:

This letter serves as a supplement to the enclosed letter submitted by DuPont to USEPA on August 10, 2006, pursuant to Section 8(e) of TSCA. In that letter, DuPont provided USEPA with certain preliminary data collected from communities in West Virginia and Ohio pursuant to a settlement of a class action lawsuit that had been brought against DuPont involving residential exposure to PFOA in drinking water.

As explained in the enclosed letter from DuPont, the Science Panel established under the settlement has asked that the parties to the settlement maintain the confidentiality of the community health study protocols[1/] developed by the Panel. DuPont, however, "informed the Science Panel that the Company would share the C-8 blood data with EPA because of the Agency's continued interest in perfluoronated substances and in particular, in nonoccupational blood data." DuPont, therefore, submitted to USEPA in its August 10, 2006, letter certain

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1/ In its August 10, 2006, letter, DuPont referred to the protocols as "drafts." The parties have since been advised by the Science Panel that the versions of the protocols distributed to the parties were, in fact, the final versions of all but one of the protocols.

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information contained within the Science Panel's community health study protocols, along with a statement from the Science Panel clarifying the preliminary nature of the data. (*See* enclosed August 10, 2006, letter and its Attachment 1) Because DuPont submitted some of the raw data, we are submitting in Attachment 2 to this letter the other raw data from the study protocols to ensure completeness of the submission. (We also have enclosed at Attachment 2 a corrected version of Figure 3.1 from DuPont's letter ("distribution of log C-8 in blood") that was blank in the version set forth on Page 8 of DuPont's letter.)

This data is submitted subject to the same disclaimer from the Science Panel as to the preliminary nature of the raw data from the community health study protocols, as set forth verbatim in Attachment 1 to DuPont's letter.

Very truly yours,

Robert A. Bilott

RAB/mdm
Enclosures

ATTACHMENT 1

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August 10, 2006

VIA FEDERAL EXPRESS

TSCA Document Processing Center (7407M)
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U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, D.C. 20004-3302
Phone: 202-564-8940

Dear 8(E) Coordinator:

Re: Perfluorooctanoic Acid (PFOA)
Preliminary Partial Non-occupational Blood Data

Through it outside counsel, E. I. DuPont de Nemours and Company (DuPont or the Company) has received copies of draft protocols that contain information regarding initial, partial PFOA blood data collected from communities in West Virginia and Ohio by an entity known as "Brookmar". DuPont has no access to the entire Brookmar data set and Brookmar is not working at the direction of DuPont. Accordingly, the Company has incomplete information. Nonetheless, the Company is providing this partial information now to the Environmental Protection Agency (EPA or the Agency) in light of the Agency's continuing interest in perfluorinated substances.

Background

In February 2005, a class action settlement consisting of several parts was approved in a lawsuit about releases of a chemical known as C-8, or PFOA, from the DuPont Washington Works facility located in Wood County West Virginia.

One major part of the settlement was the creation of a Science Panel, consisting of three epidemiologists, to conduct a community study to assist the Panel in evaluating whether there is a probable link between C-8 exposure and any human disease. Epidemiologists acceptable to both parties in the lawsuit were selected; none of the selected epidemiologists have ever worked for DuPont or with Plaintiffs' counsel. Similarly, any other experts selected by the Science Panel to help it must also be independent of DuPont and Plaintiffs and their counsel. To further ensure the independence and impartiality of the Science Panel, the settlement has specific rules about communications between the parties and the Science Panel.

The question put to the Science Panel is whether there is a probable link between C-8 and any human disease. A probable link in this setting means that given the scientific evidence available, it is more likely than not that a connection exists between C-8 exposure and a particular human disease among class members. The Science Panel is permitted to consider any evidence it believes is relevant to answer this question, but it must include an analysis of the following two

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studies: (1) an ongoing study conducted by DuPont of its workers at Washington Works and (2) a community study which the Science Panel must lead.

Another part of the settlement was a cash payment to Plaintiffs, some of which was to be used to fund community health and education projects. Plaintiffs elected, and the court approved, use of the entire cash payment to fund a Community Health Project administered by Brookmar. Brookmar is collecting data from class members through questionnaires and blood testing. This data represents a portion of what the Science Panel will evaluate to answer the question of whether a probable link exists between C-8 and human disease.

Preliminary C-8 Blood Data from Community Health Project

Outside counsel for DuPont received copies of draft protocols for a series of studies the Science Panel intends to conduct to address its charge under the class action settlement. The Science Panel reported some preliminary summaries of the C-8 blood levels in these draft protocols.[1] The Science Panel asked that the parties to the settlement, including DuPont, maintain confidentiality of these protocols at this time.

DuPont informed the Science Panel that the Company would share the C-8 blood data with EPA because of the Agency's continuing interest in perfluorinated substances and in particular, in non-occupational blood data. The Science Panel indicated that it did not realize that by sharing this preliminary data with DuPont, it would potentially become publicly available at this time. Upon learning that DuPont planned to submit the information to the Agency, the Science Panel requested that DuPont also communicate the following about the preliminary data:

> "We have prepared some outline protocols for several interlinked research components addressing the potential health effects of exposure to C8 around the Washington Works plant. 'C8 Science Panel Community Health Study: Outline Protocols; June 30 2006'
>
> These are not final but we shared them with the settling parties for the express purpose of allowing them to see the overall approach we are taking and the likely timescales for generating findings in the Community Study.
>
> Included in the protocols are some data that should under no circumstances be allowed to fall into the hands of the press, general public or general scientific community. We have received some preliminary data from Brookmar on the survey results of the C8 Health Project, understood by them and us to be confidential, and we have examined it for the purposes of helping us in developing study designs and calculated statistical power only, not to provide meaningful findings. We have included some tabulations of, for example, average blood C8 levels and some prevalences of self reported disease (though not any information on whether or not they correlate – we have not looked at that).
>
> These data were arbitrary subsets of the data as they accumulate, and are not representative of the full database, any tabulations are crude rather than adjusted so are not comparable, the different protocols used the accumulating data at

[1] Brookmar has apparently provided a subset of approximately 30,000 individuals to the Science Panel.

different times, so the data used in different tables may be different. We judge these kinds of data sufficient for our purposes of study design, but not appropriate for any kind of inference about the health or exposure of this population.

Further, complete results will be subject to release and dissemination after careful review and analysis by Brookmar (for a descriptive summary) and the Science Panel (analytical relationships). We understand that Brookmar will make available a full copy of the anonymised data to any interested parties, as soon as they have completed the assembly and quality control of the data.

We would therefore ask the settling parties' counsel not to distribute these draft protocols with the summary of some of the Brookmar data. We will issue a version of our protocols for dissemination without such results."

* * *

Communication from Science Panel to Settling Parties, dated July 19, 2006. (Full copy enclosed as Attachment 1).

To reiterate what is stated above, DuPont does not have access to the Brookmar data. DuPont also has not verified with either the Science Panel or Brookmar that the numbers reported in the draft protocols are accurate and free of typographical errors. With all of these caveats, and although DuPont does not believe the information provided herein is indicative of substantial risk information under TSCA section 8(e), DuPont submits, in Attachment 2, tables and excerpts from the draft protocols that contain information related to C-8 blood levels.

Very truly yours,

Andrea V. Malinowski

Attachments (2) – 7 pages

Attachment 1

July 19, 2006 "Note for settling parties" from the Science Panel (1 page)

Note for settling parties

We have prepared some outline protocols for several interlinked research components addressing the potential health effects of exposure to C8 around the Washington Works plant. "C8 Science Panel Community Health Study: Outline Protocols; June 30 2006"

These are not final but we shared them with the settling parties for the express purpose of allowing them to see the overall approach we are taking and the likely timescales for generating findings in the Community Study.

Included in the protocols are some data that should under no circumstances be allowed to fall into the hands of the press, general public or general scientific community. We have received some preliminary data from Brookmar on the survey results of the C8 Health Project, understood by them and us to be confidential, and we have examined it for the purposes of helping us in developing study designs and calculated statistical power only, not to provide meaningful findings. We have included some tabulations of, for example, average blood C8 levels and some prevalences of self reported disease (though not any information on whether or not they correlate – we have not looked at that).

These data were arbitrary subsets of the data as they accumulate, and are not representative of the full database, any tabulations are crude rather than adjusted so are not comparable, the different protocols used the accumulating data at different times, so the data used in different tables may be different. We judge these kinds of data sufficient for our purposes of study design, but not appropriate for any kind of inference about the health or exposure of this population.

Further, complete results will be subject to release and dissemination after careful review and analysis by Brookmar (for a descriptive summary) and the Science Panel (analytical relationships). We understand that Brookmar will make available a full copy of the anonymised data to any interested parties, as soon as they have completed the assembly and quality control of the data.

We would therefore ask the settling parties' counsel not to distribute these draft protocols with the summary of some of the Brookmar data. We will issue a version of our protocols for dissemination without such results.

If for reasons of complying with relevant laws the settling parties decide to share these tables with any regulators we would ask they attach this note of explanation.

The Science Panel
19 July 2006

Attachment 2

Tables and excerpts from the draft protocols that contain information related to C-8 blood levels.

Table 1. Descriptive statistics for the community cohort age>=20 at baseline in 2005 (n=23,942)

Mean age in 2005	46
Age <20	20%
Age 20-39	31%
Age 40-49	18%
Age 50-59	15%
Age 60-69	10%
Age 70+	6%
Median Body Mass Index	27.9
Mean C8 level	130 ppb
Median C8 level	48 ppb
Percent >=60 yrs age	20%
Percent BMI>=30	36%
Percent white	98%
Percent male	46%
Percent current smokers	26%
Percent finished college	13%

Table 2. Anticipated distribution of C8 in study participants.

C8 median	48 ppb
C8 mean	130 ppb
C8	
<10 ppb	8%
10-49	43%
50-99	20%
100-149	9%
150-199	5%
200-299	5%
300-550	5%
505+	4%

Table 1. Descriptive data on subjects>age 20 (n=23,942)

Age	
20-39	38%
40-49	23%
50-59	19%
60-69	12%
70-79	6%
80+	2%
White	98%
Female	54%
Current smoker	26%
School	
<12	11%
High School/GED	43%
Some College	34%
College degree	12%
C8 median	48ppb
C8 mean	130ppb
C8	
<10 ppb	8%
10-49	43%
50-99	20%
100-149	9%
150-199	5%
200-299	5%
300-550	5%
550+	4%
BMI mean	28.9
BMI median	27.9
BMI 30+	30%
% prevalent heart disease	8.5%
% prevalent stroke	2%
Cholesterol mean	200 mg/dl
Cholesterol median	196 mg/dl

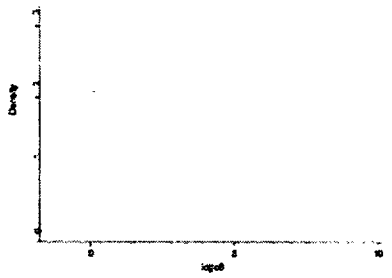
Table 3.2 Blood C8 in participants by water district reported as source of drinking water (last address, ignoring those not reporting one of the six water districts as source). Mean, median and 10th and 90th percentiles. (Units ug/1).

District of last address (DW)	N	mean(c8)	med(c8)	p10(c8)	p90(c8)
1: City of Belpre,OH	2,831	71.6	45.2	17.6	134.9
2: Tupper Plains	4,807	63.0	48.9	18.5	111.7
3: Little Hocking Water Association	4,338	396.9	290.0	83.6	820.5
4: Lubeck Public Service District	5,494	131.7	90.4	30.9	237.0
5: Mason County	3,522	19.1	15.5	7.4	34.2
6: Village of Pomeroy	734	18.6	15.6	7.1	32.6
Other	8,903	82.6	29.1	91	138.3
Total	30,629	123.0	47.8	11.7	284.9

Table 3.3 Mean, median and range within some percentile fractions (Units ug/1).

	N	mean(c8)	med (c8)	min	max
Lowest 10%	3,117	8.0	8.5	.25	11.7
Upper 10%	3,063	664.4	479	285	11391.9
Lower 50%	15,323	22.9	21.2	.25	47.8
Upper 50%	15,306	223.2	113	47.9	11391.9

Figure 3.1 Distribution of log c8 in blood



3.3 Power

Power is presented in Table 3.4 as the chance of being able to detect a significant result for a modest increase in RR (1.25) and a substantial increase in RR 2.0 for the simplest comparison between the upper and lower half of the population (with C8 in blood, mean 223 ug/l and 23 ug/l respectively). [With alpha 0.05, two sided. Calculated with `sampsize' in STATA.] Note that this may underestimate power relative to analyses that consider the full range of exposure or ordered categories, but ignores more complex models with multiple covariates which can reduce power somewhat. Nonetheless, these estimates convey a good sense of the magnitudes of association we will be capable of detecting.

Table 3.4 summary of power calculations

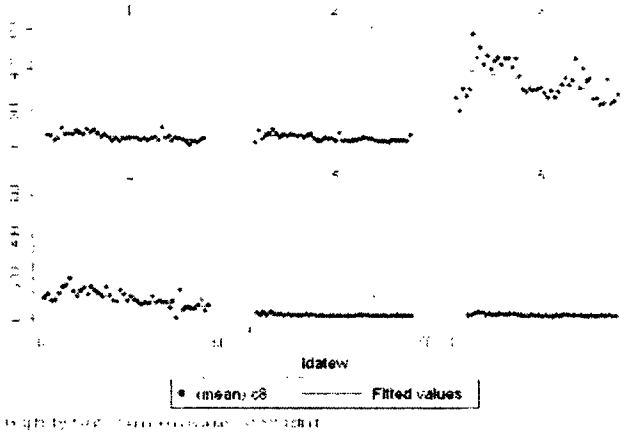
		% Power to detect RR of:	
	Expected n	1.25	2.0
Bladder	106	18	92
Breast (fem)	559	75	100
Kidney	113	19	93
Testes	59	11	68

The Science Panel also reports the following with respect to a trend observed in the C-8 blood levels:

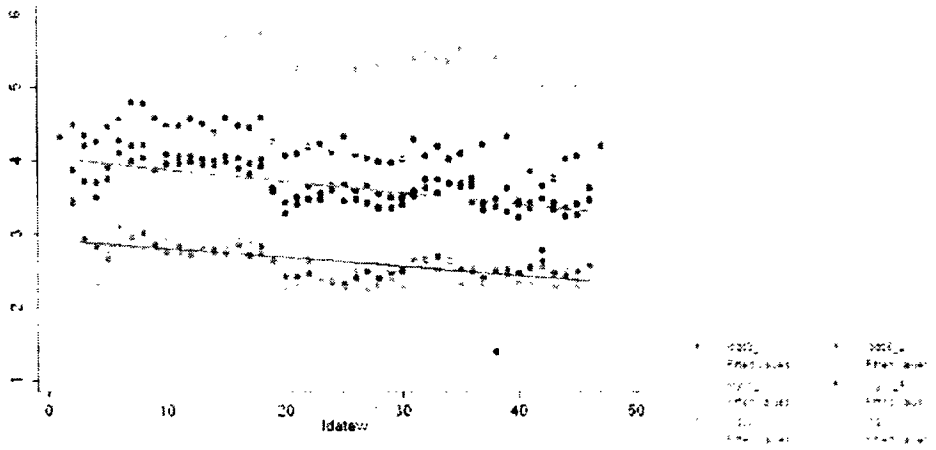
3 The C8 health project data and trends in PFOA levels in the study area

[The Science Panel has] a very detailed source of good quality data on C8 levels at an individual level by virtue of the large amount of data collected by the Brookmar team. This will be supplemented by a detailed assessment of the patterns of metabolism and clearance of C8 in the half life study component.

This data have been assembled over nearly a year and an initial examination of it reveals a significant trend in C8 by community, which has implications for the design of our study. He following figure shows the pattern of C8 levels for people classified by the current water district in which they live (after excluding those who live outside the catchment area of the 6 water districts). Each point is the average of a weeks' collection of blood samples over 47 weeks of data collection. In each water district they appear to have a downward slope.



The trends are more readily seen in the log-transformed C8 data: the following graphs illustrate the similar proportional trend in average weekly mean log c8 within each of the six water districts:



The magnitude of the slope is about a 7% drop per month:

If the within-individual trend is comparable to the observed slope for the community (i.e. the observed slope is not due to a downward trend in the proportion of individuals who happen to have relatively high C8 in blood – unlikely to have been repeated in each water district) then this would indicate a rather steep decline: the combination of reducing intake and clearance would then appear to be associated with a half life of less than a year. At this rate the c8 level in the blood has fallen by nearly 60% in a year.