

# TSCA Section 8(e) Committee Meeting

## Record of Proceedings

DRAFT 6/1/01

Date of Meeting: 5/15/01

Product/Material: PFOS and N EtFOSE

Description of information which is potentially reportable per TSCA Section 8(e)

Statistical analyses of the 2 year cancer bioassays on both compounds indicate statistical significance. See attached summaries from J. Butenhoff.

Recommendation: Report as supplemental to previous reports on PFOS and EtFOSE

Description of recommendation: REDACTED

REDACTED

List of attendees: Kathy Reed, Tom Dipasquale, Dale Bacon, Marv Case, Jeff Mandel, Georjean Adams. Guests: John Butenhoff, Geary Olsen

**Exhibit  
1783**

State of Minnesota v. 3M Co.,  
Court File No. 27-CV-10-28862

Made Available by 3M for Inspection and Copying as Confidential Information:  
Subject to Protective Order In Palmer v. 3M, No. C2-04-6309

3MA02608788

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**Initial notification to Committee :**

PFOS From John Butenhoff 5/8/01

Kathy, I reviewed the "Statistical Report of Survival, Nonneoplastic, and Neoplastic Lesions" from the two-year dietary study of PFOS in rats last Friday. The report shows significant increases in liver, pancreatic and thyroid tumors. Marv has had a chance to review the report, and I have discussed aspects of it with Jeff, Larry and Geary. Today, I forwarded the report to Dr. Jack Moore for his review and comment relative to TSCA 8(e). Hepatocellular combined adenoma and carcinoma is clearly significant in the females at the high dose, a result very similar to that obtained with N-EtFOSE at the high dose in that study. I would personally consider the responses in the males to be just over the border on the positive side, yet they certainly should be considered for submittal under TSCA 8(e). By comparison, we did not produce significant elevations in tumors in the males in the N-EtFOSE two-year study. I have prepared the following DRAFT notification letter for committee consideration. Please let me know if any clarification is necessary.

TABLE: RESULTS OF STATISTICAL ANALYSIS OF SELECTED NEOPLASTIC LESIONS FROM TWO-YEAR DIETARY STUDY OF PFOS IN RATS.

FEMALES

| Tumor                              | Control                | 0.5 ppm                   | 2 ppm      | 5 ppm      | 20 ppm              | 20 ppm Rec   |
|------------------------------------|------------------------|---------------------------|------------|------------|---------------------|--|
| Hepatocellular Adenoma             | 0/60<br>p = 0.0153*(a) | 1/50<br>NA <sup>(b)</sup> | 1/49<br>NA | 1/50<br>NA | 5/60<br>p = 0.0386* | 2/40<br>p = 0.2040 <sup>(c)</sup><br>p = 0.3050 <sup>(d)</sup> |
| Hepatocellular Carcinoma           | 0/60                   | 0/50                      | 0/49       | 0/50       | 1/60                | 0/40   |
| Hepatocellular Adenoma & Carcinoma | 0/60<br>p = 0.0057**   | 1/50<br>NA                | 1/49<br>NA | 1/50<br>NA | 6/60<br>p = 0.0204* | 2/40<br>p = 0.2040<br>p = 0.2114                               |

MALES

| Tumor                                       | Control             | 0.5 ppm            | 2 ppm              | 5 ppm              | 20 ppm              | 20 ppm Rec                         |
|---|---------------------|--------------------|--------------------|--------------------|---------------------|------------------------------------|
| Hepatocellular Adenoma                      | 0/60<br>p = 0.0276* | 3/50<br>p = 0.1345 | 3/50<br>p = 0.0689 | 1/50<br>NA         | 7/60<br>p = 0.0456* | 0/40<br>NA<br>p = 0.0240*          |
| Pancreatic Islet Cell Carcinoma             | 0/60<br>p = 0.0237* | 2/49<br>p = 0.1793 | 1/50<br>NA         | 4/50<br>p = 0.2148 | 5/50<br>p = 0.0463* | 3/40<br>p = 0.1102<br>p = 0.4972   |
| Thyroid Follicular-Cell Adenoma             | 3/60<br>p = 0.4998  | 5/49<br>p = 0.3967 | 4/50<br>NA         | 4/49<br>NA         | 4/59<br>NA          | 9/39<br>p = 0.0280*<br>p = 0.0121* |
| Thyroid Follicular-Cell Carcinoma           | 3/60<br>p = 0.2210  | 1/49<br>p = 0.3855 | 1/50<br>p = 0.2448 | 2/49<br>NA         | 1/59<br>p = 0.1734  | 1/39<br>p = 0.4280<br>NA           |
| Thyroid Follicular-Cell Adenoma & Carcinoma | 6/60<br>p = 0.2520  | 6/49<br>NA         | 5/50<br>NA         | 5/49<br>NA         | 5/59<br>NA          | 10/39<br>p = 0.0970                |

|  |  |  |  |  |  |  |             |
|--|--|--|--|--|--|--|-------------|
|  |  |  |  |  |  |  | p = 0.0125* |
|--|--|--|--|--|--|--|-------------|

- a) The p values in the control column are one-tailed for trend.
- b) "NA" indicates that data do not meet the criteria for inclusion in statistical analysis.
- c) For high-dose recovery values, the first p value is for one-tailed, pair-wise comparison to control.
- d) For high-dose recovery values, the second p value is for one-tailed, pair-wise comparison to the high-dose group.

N-Et FOSE From John Butenhoff 5/9/01

Kathy, this morning I was reviewing control incidence in a report recently received from Covance on the N-EtFOSE study tumor incidence statistics to compare with the data recently received on PFOS. I noticed that we had a significant ( $p < 0.05$ ) incidence of thyroid follicular cell adenoma in the males from the N-EtFOSE study. 3M previously reported on hepatocellular adenoma/carcinoma in the females for this study in a December 4, 2000 letter. I'm on my way out of town for a day; however, I did put together a draft for committee consideration. This draft will probably need a stronger tie to the prior submissions.

TABLE: RESULTS OF STATISTICAL ANALYSIS OF SELECTED THYROID NEOPLASTIC LESIONS IN MALES FROM TWO-YEAR DIETARY STUDY WITH N-EtFOSE

| Tumor                                       | Control 1 <sup>(a)</sup>              | Control 2 <sup>(a)</sup>  | 1 ppm      | 3 ppm                             | 30 ppm             | 100 ppm             | 100 ppm Rec  |
|---|---------------------------------------|---------------------------|------------|-----------------------------------|--------------------|---------------------|--|
| Thyroid Follicular-Cell Adenoma             | 0/55<br>p = 0.0171*<br><sup>(c)</sup> | 0/60<br>NA <sup>(d)</sup> | 0/60<br>NA | 3/50<br>p = 0.1662 <sup>(e)</sup> | 1/50<br>NA         | 6/60<br>0.0107*     | 1/40<br>NA <sup>(f)</sup><br>p = 0.1204 <sup>(g)</sup> |
| Thyroid Follicular-Cell Carcinoma           | 0/55<br>NA                            | 0/60<br>NA                | 0/60<br>NA | 0/50<br>NA                        | 1/50<br>NA         | 0/60<br>NA          | 1/40<br>NA<br>NA                                       |
| Thyroid Follicular-Cell Adenoma & Carcinoma | 0/55<br>p = 0.0155*                   | 0/60<br>NA                | 0/60<br>NA | 3/50<br>p = 0.1662                | 2/50<br>p = 0.3667 | 6/60<br>p = 0.0107* | 2/40<br>p = 0.1713<br>p = 0.2303                       |

- e) Control for 3,30,100 ppm and 100 ppm recovery dose groups.
- f) Control for 1 ppm dose group.
- g) The p values in the control column are one-tailed for trend.
- h) "NA" indicates that data do not meet the criteria for inclusion in statistical analysis.
- i) The p values under dose groups are for pari-wise comparison to the appropriate control.
- j) For high-dose recovery values, the first p value is for one-tailed, pair-wise comparison to control.
- k) For high-dose recovery values, the second p value is for one-tailed, pair-wise comparison to the high-dose group