

# FC-143 AND APME

## TOXICOLOGY RELATED ISSUES FROM 1995 TO PRESENT

01/13/1997

Roger G. Perkins

**Exhibit  
2551**

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

# APME TOXICOLOGY COMMITTEE

- DUPONT - GERRY  
KENNEDY
- ICI-UK - DAVID FARRAR
- AUSIMONT - GIUSEPPE  
MALINVERNO
- HOECHST AG - REINHARD  
JUNG
- MITENI - MARIO  
MISTRORIGO
- 3M as invited guest - ROGER  
PERKINS

01/13/1997

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# APME TOXICOLOGY COMMITTEE MEETINGS

- IN BALTIMORE, MD  
MARCH 1995
- IN GENEVA AND BRUSSELS  
IN JUNE & OCTOBER 1995
- IN ANAHEIM, CA MARCH  
1996
- PROPOSED 1997 MEETING

01/13/1997

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# APME TOX. COMMITTEE INTEREST IN FC-143

- COMPILE TOXICITY DATA  
FOR Scientific Committee for  
Food
- LIST OF ADDITIVES FOR  
PLASTICS AND COATINGS
  - INCLUDES AMMONIUM  
PERFLUOROOCTANOATE
  - INCLUDES SODIUM  
PERFLUOROOCTANOATE
    - » LIST 8 FOR SCF = substances for which  
no or only scanty and inadequate data were  
available

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# APME TOX. COMMITTEE INTEREST IN FC-143

- OUTLINE OF 3M DATA PER PTSS
- IDENTIFICATION OF DATA NEEDED
- 3M SCD COMMITS TO DOING STUDIES
- STUDIES COMPLETED AND ADDED TO PTSS
- STUDY NEEDS APPLIED TO FC-1090

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# APME TOX. COMMITTEE INTEREST IN FC-143

## ■ SCF GUIDELINES RE TOXICITY TESTS

– IF  $5 < M < 60$  MG/KG “FULL  
DOSSIER”

» 90-DAY ORAL

» 3 MUTAGENICITY STUDIES

■ GENE MUTATION IN BACTERIA

■ CHROMOSOMAL ABERRATION

■ GENE MUTATION IN  
MAMMALIAN CELLS

» STUDIES ON ABSORPTION,  
DISTRIBUTION, METABOLISM  
AND EXCRETION

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# APME TOX. COMMITTEE INTEREST IN FC-143

## ■ SCF GUIDELINES RE TOXICITY TESTS

– IF  $5 < M < 60$  MG/KG

CONTINUED

- » DATA FOR REPRODUCTION
- » DATA FOR TERATOGENICITY
- » DATA ON LONG-TERM  
TOXICITY / CARCINOGENICITY

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# APME TOX. COMMITTEE INTEREST IN FC-143

## ■ SCF GUIDELINES RE TOXICITY TESTS

– IF  $0.05 < M < 5$  MG/KG

» REDUCED EXCLUDES LAST  
THREE

## ■ SCF GUIDELINES RE TOXICITY TESTS

– IF  $M < 0.05$  MG/KG

» THREE MUTAGENICITY TESTS  
LISTED FOR “FULL DOSSIER”

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# 3M SCD ACTIONS

## ■ FURTHER MUTAGENICITY TESTING

- MOUSE MICRONUCLEUS  
14 MAY 96 REPORT DATE

- CHROMOSOMAL  
ABERRATION  
25 APR 96 REPORT DATE

## ■ MEETING ON SCF TECHNICAL DOSSIER

- NEED FOR EXTRACTION  
DATA

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# APME TOX. COMMITTEE ISSUES RE LONG-TERM DATA

- MEMBER TOXICOLOGISTS  
DISCUSS
  - 3M TWO YEAR FEEDING  
STUDY RESULTS
  - DuPont TWO YEAR FEEDING  
STUDY RESULTS

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# APME TOX. COMMITTEE ISSUES RE LONG-TERM DATA

## ■ IDENTIFY OPEN ISSUES ON MECHANISM OF TUMOR FORMATION

- CONSENSUS THAT LEYDIG  
CELL MECHANISM IS  
EXPLAINED
- CONSENSUS THAT LIVER  
TUMOR MECHANISM IS  
EXPLAINED
- CONCERN THAT ACINAR  
PANCREATIC TUMORS  
MECHANISM NOT CLEAR

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# APME TOX. COMMITTEE ISSUES RE LONG-TERM DATA

## ■ PROPOSAL FROM ICI- ZENECA

### – PREPARE PROTOCOL

- » TO OUTLINE METHODS FOR  
RESEARCH ON PANCREAS  
ACINAR CELL TUMORS
- » CONDUCT STUDIES OF  
EFFECTS OF FC-143 IN ACINAR  
CELLS

## ■ PROPOSAL PRESENTED MARCH 1996

### – NO CONSENSUS , REQUESTED REVIEW

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# 3M RESPONSE TO APME TOX. COM ISSUES RE LONG-TERM DATA

- 3M SCD ASKED FOR MORE TIME
  - FALL 1996
- DUPONT DRAFT ARTICLE ON WYETH
  - 3M TOX. SUGGESTS AS METHOD FOR STUDYING MECHANISM OF PANCREATIC TUMOR FORMATION
- DUPONT PROPOSES MONKEY STUDY
  - DECEMBER 1996 MEETING WITH CHW

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# R. JUNG QUESTIONS 17 JUNE 1996

- CAS NUMBERS ON 3M FC-143  
MSDS
- ANALYTICAL METHOD FOR  
SUBSTANCE IN BLOOD
- REVIEW OF EU R-40 LABEL  
CRITERIA
- CHROMOSOMAL ABERRATION  
ASSAY IN HUMAN VERSUS  
ANIMAL CELLS

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Tuesday, August 20, 1996

- **1a.** Discuss and resolve if the MSDSs for FC-143, 118, 1006, etc. should list cas numbers found in EINECS for the branched isomers.
- **1b.** Determine which structures cas number 3825-26-1 includes.
- **1c.** Which structures are listed on TSCA, EINECS, etc

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Tuesday, August 20, 1996

- **2.** Provide Reinhard Jung the analytical method for determining level of perfluorooctanoic acid in employee blood. They want to start monitoring of their employees; R. Jung would pass information to their physicians. Discussion between J. Mandel and their physicians is also desirable.

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Tuesday, August 20, 1996

- **3. Review the criteria for use of R-40 EU label statement and determine if FC-143 and related products need such warning for irreversible damage.**

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Tuesday, August 20, 1996

- 4. Get chromosomal aberration assay in human lymphocytes started for FC-1090 which is the sodium salt of perfluorooctanoic acid and also get okay for the same study for FX-1006.

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# 3M ACTION ON R. JUNG QUESTIONS

- AUGUST MEETING CALLED BY SCD  
ST. PAUL
  - DECISION THAT CAS NUMBERS  
ARE COMPLETE
  - SCD SEEKS CONFIDENTIALITY  
AGREEMENT FOR BLOOD  
ANALYSIS METHODS
  - REVIEW INDICATES R-40  
“POSSIBLE RISK OF  
IRREVERSIBLE DAMAGE” IS NOT  
WARRANTED
  - STUDY ON FC-1090 IN HUMAN  
LYMPHOCYTES DONE

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# PENDING ISSUES RE FC-143

## ■ APME RELATED

- STUDY OF MECHANISM OF PANCREATIC TUMORS
- COMPLETE TOXICITY SUMMARY STARTED JOINTLY BY 3M AND DUPONT
- COMPLETION OF SCF DOSSIER

## ■ 3M DUPONT RELATED

- MONKEY STUDY
- RISK ASSESSMENT

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# DYNEON INTEREST IN APME

## ■ DYNEON PERSON NOW IN APME

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