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FAX

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TO: Matt Koenings DuPont *Phone:* *FAX Phone:* (302) 999-4925	*FROM:* W. A. Weppner 3M A&CM Group 223-6S-04 St. Paul, MN 55144 *Phone:* (612) 733-6374 *FAX Phone:* (612) 736-7542

MESSAGE:

Matt Koenings:

Attached are 3Ms questions on environmental issues for our proposed meeting.

W. A. Weppner

RJZ020612

EID093150

ENVIRONMENTAL QUESTIONS:

1. site yes 3–40 ft have done at one site

1. For the purpose of defining the most representative samples for analysis by 3M, how many sites are involved and have they been characterized geologically and hydrologically? What is the depth to groundwater, depth to impermeable layer, groundwater flow rate and direction, etc.

2. Are the sites similar in regard to their characteristics (type of soil) or are the soils very different?

3. What analyses of soil and groundwater have been done and what are the results? Have the samples been analyzed for total organic fluorine? How does the concentration of FC-143 compare to the total organic fluorine concentration? What other fluorinated organics in addition to FC-143 are known or believed to be present and at what concentrations?

- been there
- C-8 only as TOF F- would do this already

4. If 3M were to perform analysis of the samples, how many samples of each type (soil, water) will there be? What is the expected lower concentration limit in the samples?

This has been sent

RJ020613

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TOXICOLOGY QUESTIONS:

1. What does DuPont hope to gain from the sub-chronic monkey capsule-feeding study with FC-143 (APFO) given that:
   a) there was an 11% (8/76) incidence of pancreatic adenoma/carcinoma in rats fed two years at 300 ppm; therefore, this effect would not be expected to occur in a 13-week monkey study and would require 80 monkeys per dose in this dose range to observe the effect in a life-time study in monkeys;
   b) a 13-week study in monkeys is not likely to produce observable pancreatic effects since pancreatic effects in rat are observed only after two months of feeding with the Wyeth compound, a much stronger peroxisome proliferator than APFO;
   c) the mechanism by which DuPont feels APFO/CCK may be related to production of pancreatic tumors is not fully understood and, therefore, how will a sub-chronic monkey study help to elucidate that mechanism without additional background research?

2. What risk issues is DuPont concerned about with respect to APFO and how are these reflected in the endpoints and hypotheses DuPont wishes to test in a sub-chronic study in monkeys?

3. Relative to the multiple effectors on hormonal levels, does DuPont feel comfortable with the validity of using hormone levels generated in a sub-chronic monkey study to adequately assess a health effect endpoint?

STEWARDSHIP QUESTIONS:

1. What is life cycle exposure analysis of APFO after it is received by DuPont?

2. What are workplace controls throughout manufacture and formulation?

3. What are disposal and recycling methods used to reduce environmental exposures?

4. How does DuPont control its formulators?

5. What are the consumer concerns with PTFE? And how does it relate?

6. What were FDA's concerns with PTFE's food additive application?

7. Could residual APFO (when heated) go into food and be eaten?

8. What about other PTFE applications, i.e.: tape? Will APFO be released?

9. We would like an exposure analysis (i.e.: concerns) split out for APFO by physical form? (FC-143 vs. FC-118)

10. Does DuPont supply explicit instructions for formulators on handling and disposal?

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