AR226-1318

6pp

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

8EHQ-0503-00373

8EHQ-80-373

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

EPA-OTS

0008118854R

May 22, 2003

DuPont Haskell Laboratory
Attn: A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs and Occupational Health
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

RECEIVED
OPPT NCIC
03 MAY 22 PM 5:03

SUBJECT: TSCA 8(e) Reporting Requirements for PFOA Information

Dear Dr. Kaplan:

In a recent report by the Environmental Working Group (EWG) on risks associated with perfluorooctanoic acid (PFOA), posted on the internet (http://www.ewg.org/reports/pfcworld/), and in a letter to Administrator Whitman alleging reporting violations of TSCA Section 8(e) (enclosed), there is a reference to a "Personal and Confidential" DuPont document containing information on PFOA blood levels in female workers at a DuPont plant in West Virginia in 1981 (enclosed). This one-page DuPont document also notes that PFOA was found in the umbilical cord blood from one baby and in the blood of another baby, both of whom were born to women working in the West Virginia plant. According to this same DuPont document, among the seven individuals listed in the table one gave birth to a child with an unconfirmed eye and tear duct defect and a second individual gave birth to a child with a nostril and eye defect. The EWG report further states that in 1981 DuPont reassigned 50 female workers at the plant to reduce PFOA exposure. In addition, the EWG report also describes DuPont studies of PFOA contamination of drinking water supplies in areas surrounding the Parkersburg, West Virginia plant.

RECEIVED
OPPT NCIC
2003 JUN -4 PM 12:44

As you know, TSCA section 8(e) states, "Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

Assuming that the information described above is accurate and was in DuPont's possession since 1981, please provide the contemporaneous logic for DuPont's decisions not to submit to EPA under TSCA section 8(e) the reports of (1) PFOA blood monitoring data on female workers and

their offspring and (2) human developmental effects (a) in 1981 and (b) subsequently as additional data on PFOA's hazards and exposures (including the drinking water data related to its West Virginia plant, the 3M blood monitoring data, the 2-generation reproductive toxicity study, etc.) were accumulated. We are concerned that the blood and umbilical cord monitoring data, together with the known or suspected toxicity of PFOA and other exposure data on PFOA, may present a TSCA 8(e) reporting obligation. In addition, please provide the drinking water data to the Agency and provide an explanation as to why it was not submitted when Dupont obtained the data. We request a response to this letter within 30 days.

Please address your response to:

Document Processing Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

Deliveries:
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Questions regarding this request should be directed to Mr. Terry O'Bryan of my staff at (202) 564-7656 or email OBRYAN.TERRY@EPA.GOV

Sincerely,

Richard H. Hefter, Chief
High Production Volume Chemicals Branch

Enclosures

cc: Charles Auer
Oscar Hernandez
Terry O'Bryan

ENVIRONMENTAL WORKING GROUP

1436 U Street NW, Suite 100
Washington, DC 20009 USA

t: 202.667.6982
f: 202.232.2592
w: www.ewg.org

April 11, 2003

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Washington, D.C.

cc: to: Steve Susie Charlie Margaret Priscilla Zelma - Please control to STPT

Re: DuPont's failure to submit key health studies under the requirements of TSCA 8(e), 15 U.S.C. § 2607(e).

Dear Administrator Whitman:

As your Agency moves forward with its assessment of public health risks posed by the Teflon-associated chemical known as PFOA (perfluorooctanoic acid, also called C8), we write to notify you of apparent violations of reporting requirements under Section 8(e) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2607(e), by a leading manufacturer and user of PFOA, DuPont, that may be hindering your assessment. We request that you investigate these potential violations of law by DuPont, and require full submission of the relevant studies to the public record to allow for an accurate assessment of the health risks posed by this persistent global pollutant that widely contaminates human blood. Given the nature and seriousness of the omissions, we recommend that the Agency levy the maximum allowable penalty under the law, a $25,000 fine per day to account for civil violations pursuant to 15 U.S.C § 2615 (a). We also ask that you investigate potential criminal violations for DuPont's knowing and willing failure to produce these studies, which would also subject the company to a maximum daily fine of $25,000. Id. at § 2615 (b).

In a 1981 internal company study (attached as Exhibit A) DuPont found quantifiable levels of PFOA in umbilical cord blood from one baby, and the blood of another baby, both of whom were born to women working in the company's Teflon plant in Parkersburg, West Virginia. This study provided evidence that PFOA crosses the placenta and exposes a fetus in utero, at a time when DuPont had accumulated a significant body of knowledge on the toxicity of PFOA.

The study documentation, made public through litigation, shows that DuPont measured PFOA in the blood of eight pregnant women employed at the plant, and for seven of these women recorded information on the baby's health after birth. DuPont found quantifiable levels of PFOA in the blood of seven of eight women tested, at concentrations ranging up to 2.5 parts per million (ppm). DuPont found PFOA in umbilical cord blood from one baby at a concentration of 0.055 ppm, and in the blood of another baby at a concentration of 0.012 ppm. The study documentation shows that two of seven women gave birth to babies with birth defects, one an "unconfirmed" eye and tear duct defect, and one a nostril and eye defect. That same year, DuPont reassigned 50 women at the plant to reduce PFOA exposure. We have

thoroughly reviewed 8(e) submissions from DuPont regarding PFOA, and find no record of this study in the Agency's files.

TSCA requires that a company inform the Administrator when it finds information "that reasonably supports the conclusion that such substance...presents a substantial risk of injury to health." 15 U.S.C § 2607(e). Given the unique susceptibility of a fetus to permanent health harms from exposures to industrial chemicals, the finding of an industrial chemical in umbilical cord blood inherently qualifies as "information that reasonably supports the conclusion that such substance...presents a substantial risk of injury to health..." and therefore should trigger a submission of the study to EPA under the provisions of TSCA 8(e). In the case of DuPont's 1981 blood study, however, the company also possessed at the time a significant body of knowledge on PFOA's toxicity that further supported what should have been a reasonable conclusion that the blood tests indicated a substantial risk to health.

According to a 1961 internal company memorandum on the toxicity of C8 and related chemicals, another document made public through litigation, a DuPont toxicologist found that "C8 and C9 acids... have the ability to increase the size of the liver of rats at low doses," and further recommends that "all of these materials...be handled with extreme care. Contact with the skin should be strictly avoided" (DuPont 1961). Between 1961 and 1981 DuPont and its PFOA supplier (3M) conducted or summarized 32 additional PFOA toxicity studies in dogs, rats, monkeys, guinea pigs, rabbits, and mice (Bilott 2002).

Among other studies that DuPont failed to submit to EPA under requirement of law are the company's studies of PFOA contamination in drinking water supplies in areas surrounding its Parkersburg, West Virginia plant (see DuPont documents at EWG 2002). Upon information and belief, DuPont's 1981 study of PFOA in babies' blood, and their finding of PFOA contamination in tap water, are just two of the health and safety studies conducted by DuPont beginning at least 22 years ago that the company failed to submit to EPA under the requirements of TSCA Section 8(e). 15 U.S.C § 2607(e).

We appreciate your prompt attention to the concerns we raise in this letter, and hope that the full record of PFOA's toxicity to humans will soon be available to the public and Agency as you proceed with your assessment of human health risks posed by the chemical.

Sincerely,

Kenneth A. Cook
President, Environmental Working Group

cc: Charles O. Holliday, Jr., Chairman & CEO, DuPont
Steve Johnson, EPA's Assistant Administrator for Prevention, Pesticides, and Toxic Substances

References

Bilott, R. 2002. Letter from Robert A. Bilott of Taft, Stettinium, & Hollister LLP to IRIS Submission Desk. IRIS Submission Inventory for Perfluorooctanoic Acid – Ammonium Salt. April 12 2002.

DuPont. 1961. Internal memo Re Toxicity of Teflon® Dispersing Agents.

Environmental Working Group (EWG). 2002. DuPont Hid Teflon® Pollution for Decades. Available online at http://www.ewg.org/policymemo/20021113/20021213.php. December 12 2002.

Attachment

Exhibit A. DuPont. 1981. Births and Pregnancies. (Documentation of DuPont study of PFOA in the blood of female employees and their babies.)

Mints type only employee number not name

PERSONAL & CONFIDENTIAL

C-8 BLOOD SAMPLING RESULTS

Births and Pregnancies

Current PPM C-8 in Blood (April 1981)	Status
0.45	Normal child - born June 1980. Transferred out of Fluorocarbons 4/79.
0.28	Normal child - born April 1981.
0.078	Normal child - born April 1981. Umbilical cord blood 0.055 ppm.
1.5	~~Five months pregnant.~~ On pregnancy leave
0.013	~~Five months pregnant.~~ Normal child - born August 1
2.5*	Child - 2 plus years. Unconfirmed eye and tear duct defect.
0.048	Child - 4 months. One nostril and eye defect. Babies blood 0.012ppm
<.007	Normal child - born July 1981

*Current blood level - in fluorocarbons area only one month before pregnancy.

RDI:ldr