WEST VIRGINIA DEPARTMENTS OF ENVIRONMENTAL PROTECTION

and

HEALTH AND HUMAN RESOURCES

PUBLIC MEETING

Regarding C8

MAY 15, 2002

6 – 8 pm

BLENNERHASSETT JR HIGH SCHOOL

What is C8?

- ammonium perfluorooctanoate (APFO or PFOA)
- fluorocarbon surfactant
- used by DuPont since 1950's at Washington Works plant, WV
- used in production of fluoropolymer resins and finishes such as Teflon

IMPETUS FOR INVESTIGATION

- C8 found in Lubeck Public Water Supply
- Toxicity of similar compound PFOS
- Legal Action – letter March 2001

CONSENT ORDER November 2001
WVDEP & DHHR, and DuPont

CONSENT ORDER 2002
EPA and DuPont
(alternate water – 14 ppb interim)

CONSENT ORDER November 2001
WVDEP & DHHR, and DuPont

established –

- C8 Assessment of Toxicity Team (CATT)
- Groundwater Investigation Steering Team (GIST)

and DuPont must -

- Reduce total emissions by at least 50% by end of 2003 from 1999 levels (air and water)
- Air emissions capped at 2000 levels
- Ageed to abide by the Screening Levels developed by the CATT; CATT number replaces interim alternate water

C8 Assessment of Toxicity Team (CATT)

- Risk Communication

  Marshall University – Dr James Becker

  WVDEP - Dr Dee Ann Staats

- Development of Risk Factors (oral, inhalation, dermal) and Screening Levels (air, water, soil) for C8

  Toxicology Excellence for Risk Assessment **(TERA)**

  WVDEP - Dr Dee Ann Staats

- Advisors - EPA, WVDHHR, DuPont

- Reimbursement to WV - $ 250,000 DuPont

CATT TOXICOLOGISTS

WV

DEP – Dee Ann Staats, Ph.D.

TERA - Michael Dourson, Ph.D.

Joan Dollarhide, MS, MTSC, JD

Andrew Maier, Ph.D., CIH

DHHR – ATSDR - John Wheeler, Ph.D.

EPA – Jennifer Seed, Ph.D.

John Cicmanec, DVM, MS

Samuel Rotenberg, Ph.D.

DuPont – Gerald Kennedy

Am Health Found. -John Whysner, M.D., Ph.D., D.A.B.T

CATT Toxicologist's Meeting

May 6 & 7, Cincinnati, OH at EPA

Others Attending -

James Sferra, MS, OEPA (observer)

John Buttenhoff, Ph.D. 3M (study scientist)

Dan Briggs, Ph.D., D.A.B.T. (minutes)

Meeting held pursuant to Consent Order, part of Enforcement Action – only applies to DuPont in WV

Not developing a regulatory standard – requires legislation

GENERAL PROCESS for DETERMINING RISK FACTORS AND SCREENING LEVELS for C8

- Review Toxicology Data Individually
- TERA reviews data in-depth and identifies potential critical studies, spreadsheet of critical effects and doses
- Provide TERA's info to group for in-depth review individually
- Meet to go over info together and build consensus on Risk Factors and Screening Levels

Potential Key Studies for the Oral RfD:

1. 3M Corporation. 1983. Two year oral (diet) toxicity/carcinogenicity study for fluorochemical FC-143 in rats. V. 1-4. Riker Experiment No. 0281CR0012. St. Paul, MN: Riker Laboratories. (file: 226-0437)
2. Goldenthal, E.I. 1978. Ninety day subacute rat toxicity study. Final report. St. Paul, MN: International Research and Development Corporation, 3M Corporation.
(file: 226-0255)
3. Palazzolo, M.J. 1993. 13-week dietary toxicity study with T-5180, ammonium perfluorooctanoate (CAS No. 3825-26-1) in male rats. Laboratory ID No. HWI 6329-100. Madison, WI: Hazelton Laboratory, 3M Corporation.
(file: 226-0449)
4. Thomford, P.J. 2001. 26-week capsule toxicity study with ammonium perfluorooactanoate (APFO) in cynomolgus monkeys. Laboratory ID No. 6329-231; Sponsor ID No. 3M T-6889.3. Madison, WI: Covance Laboratories, Inc.
(file: 6329-231)
5. York, R.G. 2002. Oral (gavage) two-generation (one litter per generation) reproduction study of ammonium perfluorooctanoate. Final Report. Laboratory ID No. 418-020.

Potential Key Studies for the RfC:

6. Kennedy, G.L., Jr., G.T. Hall, M.R. Brittelli, J.R. Barnes and H.C. Chen. 1986. Inhalation toxicity of ammonium perfluorooctanoate. Food Chem. Toxicol. 24(12): 1325-1329.

Potential Key Studies for the Dermal RfD:

7. Kennedy, G.L., Jr. 1985. Dermal toxicity of ammonium perfluorooctanoate. Toxicol. Appl. Pharmacol. 81(2): 348-355.

Potential Human Studies for Derivation of RfD/RfCs:

8. Gilliland, F.D. and J.S. Mandel. 1996. Serum perfluorooctanoic acid and hepatic enzymes, lipoproteins, and cholesterol: A study of occupationally exposed men. Am. J. Ind. Med. 29: 560-568. (file: 226-0475)

9. Olsen, G.W., F.D. Gilliland, M.M. Burlew, J.M. Burris, J.S. Mandel, and J.H. Mandel. 1998. An epidemiological investigation of reproductive hormones in mean with occupational exposure to perfluorooctanoic acid. JOEM 40(7): 614-621. (file: 226-0474)

10.Olsen, G.W., J.M. Burris, M.M. Burlew, and J.H. Mandel. 2000. Plasma cholecystokinin and hepatic enzymes, cholesterol and lipoproteins in ammonium perfluorooctanoate production workers. Drug Chem. Toxicol. 23(4): 603-620. (file: 226-0476)

CATT Toxicologist's Meeting Results

- Dermal Risk Factor - Data Inadequate for Development; not unusual; use Oral Risk Factor as surrogate

- Inhalation Risk Factor - still in development

  Data being collected for model parameters such as particle size distribution

  Expect to be finished in 3 - 4 weeks

CATT Toxicologist's Meeting Results

Oral Risk Factor = 0.004 mg-Kg/day

- Unanimous decisions
- High Degree of Confidence that won't change significantly in the future
- EPA Region 9 methodology used to calculate screening levels based on oral risk factor

Screening Level for Water = 150 ppb

Screening Level for Soil = 240 ppm

Alternative Derivations of the RfD and RfC Values for C8									
Reference	**Critical Effect**	**Critical Effect Level[a]**	**UF A**	**UF H**	**UF L**	**UF S**	**UF D**	**Composite UF[b]**	**RfD/RfC**
Oral Studies									
Palazzolo et al. (1993)[c] 90-day rat study	Increased relative liver weight with histopathology in male rats	0.47 (NOAEL in males) 0.72 (BMDL)	10	10	1	1	1	100	0.005 0.0072
York et al. (2002) Two-Generation rat study	Increased liver weight in male rats, supported by histopathology at higher doses.	1 (LOAEL in males)	10	10	3	1	1	300	X
	Increased liver weight in male rats, supported by histopathology at higher doses (histopathology was not examined at the lowest dose, but incidence of hypertrophy was 100% at next highest dose).	0.42 (BMDL in males)[d]	10	10	1	1	1	100	0.004
3M (1983) Two-year rat study	Tubular hyperplasia of the ovarian stroma and clinical signs (ataxia) in female rats.	1.6 (LOAEL in females) 1.57 (BMDL)	10	10	1	1	1	100	0.0157
	Hepatic megalocytosis in male rats.	0.73 (BMDL in males)	10	10	1	1	1	100	0.0073
Thomford et al. (2001)[e]26-week cynomolgus monkey study	Decreased thyroid hormone levels in male cynomolgus monkeys, and supported by a [illegible]AEL at the same dose for [illegible]ical signs of toxicity in the [illegible]ritical rhesus monkey [illegible]ly (Goldenthal et al.,	3 - 10 (LOAEL in males)	10	10	3	3	1	1000	0.003 - 0.01

Why the difference in Water Screening Level?

In General -

1. **The CATT Level is based on new data.**

2. **The CATT Level considers all the key toxicity studies.**

How does the C8 RfDo compare to that for other chemicals?

The average EPA-developed oral RfD is 0.02 mg-Kg/day which is 5 times higher than C8's of 0.004 mg-Kg/day.

Therefore, C8's risk factor is more conservative or health protective than that for the average chemical.

How does the Water Screening Level for C8 compare to that for other chemicals?

Chemical	Water Screening Level (ug/L)
C8	150
Cyanide	11
Strychnine	11
Formaldehyde	5,500
Acetone	610
DDT	0.2

What's Next for the CATT?

1. Finalize the Inhalation Reference Dose and determine the Ambient Air Screening Level
2. Ecological Risk Assessment
3. Continue Public Information Meetings
4. Training for Local Physicians