

**Meeting with
Office Of Environmental Health Hazard
Assessment
regarding
PERFLUOROOCCTANOIC ACID
(PFOA)**

Sacramento, California

June 27, 2006

Meeting Regarding PFOA

■ PARTICIPANTS

■ OEHHA

- Joan M. Denton, Ph.D.
Director
- Val F. Siebal
Chief Deputy Directory
- George Alexeeff, Ph.D.
Deputy Director, Scientific Affairs
- Lauren Zeise, Ph.D.
Branch Chief, Reproductive & Cancer Hazard Branch
- Martha Sandy, Ph.D.
Chief, Cancer Toxicology & Epidemiology Section
- Carol Monahan-Cummings
Chief Counsel

■ DUPONT

- Susan M. Stalnecker
Vice President, Risk Management
- Robert W. Rickard, Ph.D.
Science Director, Haskell Laboratory
- David W. Boothe
Global Business Manager, Fluoroproducts
- William P. Raiford, Ph.D.
Global Technology Manager, Fluoroproducts
- Thomas R. Jacob
Government Affairs Manager, Western Region
- Arthur Lawyer, Ph.D.
Technology Sciences Group Inc.
- Jay Murray, Ph.D.
Murray and Associates
- Stanley W. Landfair
McKenna Long & Aldridge LLP

Meeting Regarding PFOA

■ AGENDA

- Background on PFOA
- Studies Assessing Health Effects of Exposure to PFOA
- Expedited Consideration of PFOA for Listing Under Proposition 65 Is Unnecessary and Inappropriate

Expedited Consideration is Unnecessary and Inappropriate

1. The Petition should be considered in the context of the proper criterion for listing a chemical as “known to the State to cause cancer”

■ Petition:

“Sufficient evidence of carcinogenicity exists from studies in experimental animals. [This] means studies in experimental animals indicate that there is an increased evidence of malignant tumors or combined malignant tumors in multiple species or strains, in multiple experiments (*e.g.*, with different routes of administration or using different dosing levels), or, to an unusual degree, in a single site with regard to incidence, site or type of tumor, or age at onset.”

Cal. Code Regs., *tit. 22*, section 12306(e)(2).

■ Proper Criterion:

“clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer.”

Cal. Code Regs., *tit. 22*, section 12305(a)(1); *see also* Cal. Health & Safety Code section 25249.8(b).

■ PFOA should not be listed under either criterion

Expedited Consideration is Unnecessary and Inappropriate

1. Petition should be considered in the context of the proper criterion for listing a chemical as “known to the State to cause cancer”
 - Not “clearly shown” to cause cancer
 - Not genotoxic
 - Benign tumors only (rats)
 - One sex, one species
 - Peroxisome proliferator (relatively weak PPAR α activator)
 - No human evidence of carcinogenicity
 - CIC listing criteria: “if the weight of evidence *clearly shows* that a certain chemical causes *invasive* cancer in humans, or that it causes *invasive* cancer in animals (*unless the mechanism of action has been shown not to be relevant to humans*), the committee will normally identify that chemical for listing.”

Expedited Consideration is Unnecessary and Inappropriate

1. Petition should be considered in the context of the proper criterion for listing a chemical as “known to the State to cause cancer”

- Not a high priority according to OEHHA’s 2004 Prioritization Procedure
 - Data on PFOA are not consistent with the provisions for expedited review in the Prioritization Procedure
 - No new carcinogenicity studies or compelling reason to warrant expedited review
 - Under the normal Prioritization Procedure, PFOA would not be a high priority since it would not pass through the initial epidemiological screen, which requires:
 - “chemicals with epidemiological evidence suggesting they cause cancer”
 - “very strong evidence from animal studies” in the absence of positive epidemiology data
 - “It is unlikely that chemicals will be proposed for CIC ... review that have been recently reviewed by an authoritative body and found to have insufficient evidence of carcinogenicity or reproductive toxicity.”

Expedited Consideration is Unnecessary and Inappropriate

2. Claims regarding scientific data are not valid

- Petition:

“studies have documented [that PFOA] causes liver, pancreatic and testicular cancer in animals”

- Fact:

- ✦ Data showed increase in benign tumors

Expedited Consideration is Unnecessary and Inappropriate

2. Claims regarding scientific data are not valid

■ Petition:

“animals studies show that PFOA meets criteria for listing under Proposition 65”

■ Fact:

- ✦ Animal studies do not support listing under criterion at Cal. Code Regs., *tit. 22*, section 12305(a)(1)

Expedited Consideration is Unnecessary and Inappropriate

3. Claims for urgency are not valid

■ Petition:

“widespread consumer exposure from a variety of products, including pots and pans”

■ Fact:

- ✦ Trace levels of PFOA detected in end-use articles that were tested, but only under extreme testing conditions
- ✦ Based on the exposure assessment and risk characterization:
 - Margins of Exposure (MOE; based on reasonable maximum exposure numbers) for all articles tested ranged from 30,000 to 9 billion
 - PFOA was below detectable levels in coated cookware, non-woven medical garments and some textiles.

Expedited Consideration is Unnecessary and Inappropriate

3. Claims for urgency are not valid

■ Petition:

- ▶ Environmental persistence creates urgency

■ Fact:

- ▶ Persistence in the absence of carcinogenicity is not relevant
 - No chemical has received an expedited review based on persistence
 - Persistence is not recognized in OEHHA's Prioritization Guidelines

Expedited Consideration is Unnecessary and Inappropriate

3. Claims for urgency are not valid

■ Petition:

“slow-moving agencies fail to provide protection” . . . “EPA . . . remains in final review process with no estimated date for finalization”

■ Fact:

- Federal agencies are moving rapidly and responsibly (petitioners simply don't like results)
 - FDA has evaluated cookware and food-related paper coatings
 - EPA carcinogenicity review is progressing in timely manner

Expedited Consideration is Unnecessary and Inappropriate

3. Claims for urgency are not valid

■ Petition:

“widespread and continuing exposure . . . warrants an abbreviation of the typical prioritization procedures to protect public health”

■ Fact:

- ✦ Exposure in the absence of carcinogenicity is irrelevant.
- ✦ Voluntary reduction programs initiated by US EPA
 - Reductions of PFOA emissions from manufacturing facilities by 95% by 2010

Expedited Consideration is Unnecessary and Inappropriate

3. Claims for urgency are not valid

- “EPA has no information linking current levels of PFOA in the blood of the general public to any adverse health effects in people. Additional study is still needed to understand these persistent chemicals. While information is being developed, EPA is taking the prudent step of seeking to reduce possible sources now, to avoid potentially larger future problems.” **Non-ECA PFOA Information Forum, U.S. EPA, Washington, DC June 8, 2006**
- “In the year and a half since the draft assessment was submitted to the SAB Panel, a considerable amount of additional research has been initiated, and some has been completed. Some of this new research may impact the Panel’s assessment of PFOA. For this reason, it is premature to draw any conclusions on the potential risks, including cancer, from PFOA until all of this new testing is complete and the data are integrated into the risk assessment.” **EPA web site, <http://www.epa.gov/oppt/pfoa/pfoarisk.htm>**

Expedited Consideration is Unnecessary and Inappropriate

3. Claims for urgency are not valid

- “Although our risk assessment activities are not complete and new data may change the current picture, to date EPA is not aware of any studies specifically relating current levels of PFOA exposure to human health effects.” **U.S. EPA Administrator Stephen L. Johnson, Letter to DuPont, Jan. 25, 2006**
- "The agency has information based on animal studies and toxic effects in animals, [but] we have no information at this point that would lead us to believe there is a significant human health impact.” **Susan Hazen, Acting Administrator of EPA Office of Prevention, Pesticides and Toxic Substances, Dec. 14, 2005**

Expedited Consideration is Unnecessary and Inappropriate

4. Expedited consideration is not a good use of OEHHA and CIC resources

■ Petition:

Requests advanced consideration to protect public health on assertion that PFOA “meets the criteria for listing under the standard set forth at 22 CCR section 12306(e)(2)”

■ Fact:

- ▶ Systematic consideration under proper criteria would not support listing
 - Present animal studies do not support listing
 - Epidemiological studies do not support listing

Expedited Consideration is Unnecessary and Inappropriate

- **Does not meet criteria for expedited review or high priority**
- **Petition not consistent with statute and state's process**
- **Petition creates and is based on false controversies**
- **Reviewed by EPA and FDA**
- **No new carcinogenicity studies**
- **No increase in malignant tumors in animals**
- **No evidence of carcinogenicity of PFOA in humans**
- **Exposures pose negligible hazard (MOEs 30,000 to 9 billion)**