Petition for Expedited CIC Consideration of Perfluorooctanic Acid (PFOA)

Martha Sandy, Ph.D., Chief
Cancer Toxicology and Epidemiology Section
Reproductive and Cancer Hazard Assessment Branch
Petitioners for Expedited CIC Consideration of PFOA

- United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union
- AFL-CIO, CLC
- Sierra Club
- Environmental Law Foundation
- Environmental Working Group
- U.S. Public Interest Research Group
- Environment California
- Natural Resources Defense Council
Petitioner’s Basis for Expedited Consideration

- Causes cancer at multiple sites in animals
- U.S. EPA Science Advisory Board (SAB)
  - Likely human carcinogen
- Ongoing public debate about the level of cancer risk
- Widespread consumer exposure in California
  - PFOA detected in blood in children and adults
U.S. EPA and its Science Advisory Board

• **U.S. EPA Draft Risk Assessment**
  — Jan. 4, 2005: “Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential”

• **SAB Review**
  — May 30, 2006: “Likely to be carcinogenic to humans”

• **U.S. EPA response to SAB:**
  — June 20, 2006: Integrate new toxicity testing; seek second SAB review

• **U.S. EPA PFOA Global Stewardship Program**
  — Jan. 25, 2006: Voluntary reduction of 95% of PFOA releases and presence in products by 2010, elimination by 2015

➢ **U.S. EPA nominates for testing by NTP a class study of perfluorosulfonates, carboxylic acids and telomers**
  — Aug. 7, 2003: Toxicity of PFOA “includes liver toxicity, immunotoxicity, cancer (liver, pancreatic, and Leydig cell tumors), and developmental toxicity”
Perfluorooctanoic Acid (PFOA) & Perfluorooctane Sulfonate (PFOS)

**PFOA**

- Formula: $\text{C}_8\text{H}_{15}\text{O}_2$
- Structure:

**PFOS**

- Formula: $\text{C}_8\text{F}_{17}\text{O}_3\text{S}^-$
- Structure:

Free acid $\ X = \text{OH}$
Ammonium salt $\ X = \text{ONH}_4$
Uses of PFOA and its Salts

- **Production of fluoroelastomers & fluoropolymers**
  - Polytetrafluoroethylene (Teflon®)
  - Polyvinylidene fluoride

- **Consumer products**
  - Coatings on paper, textiles, carpet
  - Personal care products
  - Nonstick coatings on cookware

- **Industrial sectors**
  - Automotive
  - Aerospace
  - Chemical
  - Electrical
  - Electronic
  - Medical
  - Building/construction
PFOA & PFOS Exposure

• **Worldwide distribution – increasing levels in:**
  — Soil, water, and air
  — Wildlife and general population

• **Very stable in the environment**
  — No known environmental breakdown mechanism for PFOA

• **Persistent in humans**
  — Not metabolized
  — High affinity for proteins
  — Distributes to liver, plasma, and kidney
  — Enterohepatic circulation
  — PFOA human serum elimination half-life: ~4 years
# PFOA in the U.S. Population

**NHANES 2001-2002, Mean Levels**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Race/Ethnicity</th>
<th>ng/mL (ppb)</th>
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<tbody>
<tr>
<td><strong>Men</strong></td>
<td>Non-Hispanic white</td>
<td>6.98</td>
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<tr>
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<td>Non-Hispanic black</td>
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<td></td>
<td>Mexican American</td>
<td>2.89</td>
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<tr>
<td><strong>Women</strong></td>
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<tr>
<td></td>
<td>Non-Hispanic black</td>
<td>2.85</td>
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<tr>
<td></td>
<td>Mexican American</td>
<td>2.08</td>
</tr>
</tbody>
</table>

Calafat et al. 2006
Human Cancer Epidemiology

• **Retrospective cohort mortality studies of fluorochemical production workers**
  
  — Minnesota: Gilliland and Mandel (1993), as reported by U.S. EPA
  
  • Increased risk of prostate cancer correlated with employment duration
  
  • Different exposure metric in follow-up, no increase in prostate cancer reported (Alexander et al., 2001)

  — West Virginia: DuPont (2003), as interpreted by U.S. EPA
  
  • Increased bladder and kidney/urinary cancer

• **SAB: “human data are ambiguous”**
Long-term Feeding Studies* in SD Rats (as reported by U.S. EPA SAB)

“3M Study”: male and female rats (Sibinski, 1987)
- Testes: Leydig cell tumors
- Liver: Hyperplastic nodules in high dose males
- Pancreas: Acinar cell hyperplasia
- Mammary: Fibroadenoma

“DuPont Study”: male rats (Cook et al., 1994; Biegel et al., 2001)
- Testes: Leydig cell tumors
- Liver: Adenomas
- Pancreas: Acinar cell adenomas; progression to carcinoma observed

*administering PFOA ammonium salt
Mechanistic Issue

• U.S. EPA postulated peroxisome proliferator-activated receptor alpha (PPAR-alpha) agonism mode of action (MOA) for:
  — Tumor triad (liver adenomas, Leydig cell tumors, pancreatic acinar tumors)

• SAB concluded:
  — Consolidation of liver, Leydig cell and pancreatic tumors into a triad MOA is not justified
  — Available evidence inadequate to support PPAR-alpha MOA for Leydig cell and pancreatic acinar tumors
  — PPAR-alpha MOA is plausible for liver tumors, but insufficient data exist to conclude that this is the sole mechanism in liver
Conclusion

- Eleven groups petitioned for expedited CIC consideration of PFOA
  - Primary basis cited by petitioner:
    - U.S. EPA SAB finding that PFOA is likely human carcinogen
    - “causes liver, pancreatic and testicular cancer in animals”
    - Widespread human exposure; persistence in human tissue
  - U.S. EPA status
    - U.S. EPA will revise the assessment
    - Revised assessment will undergo US EPA SAB review
    - US EPA requested NTP test perfluorinated compounds
- Other Authoritative Bodies
  - NTP studying perfluorinated compounds per EPA request
  - A 4-week pharmacokinetic study is being planned for PFOA
- CIC discussion:
  Should PFOA be considered at a future meeting for potential listing as known to cause cancer?