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AR 226 - 1094

MR 54370

The Society of the Plastics Industry, Inc.

Suite 600K
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Washington, D.C. 20006

Allen C. Weidman
Executive Director

Friday, April 26, 2002

Ms. Mary Dominiak
Chemical Control Division (7405M)
US Environmental Protection Agency
Room 4410-M
1201 Constitution Avenue, N.W.
Washington, DC 20460

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OPT CBI
2002 APR 29 11:06

Subject: Fluoropolymer Manufacturers Group Presentation Slides

Dear Ms. Dominiak:

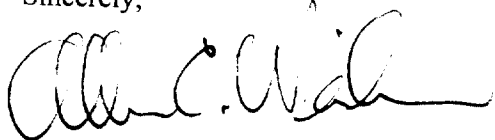
On behalf of the Fluoropolymer Manufacturers Group (FMG) I am sending you the original and redacted copies of the presentations given today by David Rurak and Gerald Kennedy.

Some CBI notes:

1. This letter is not CBI.
2. The copy of the sanitized version of the presentation is so marked and three blank slides were inserted to replace the CBI redacted slides.
3. The copy of the presentation containing TSCA CBI is contained in the inter envelope and is so marked on the envelope and the title page of the presentation.

I hope that this information is sufficient for your needs as this time. If there are any other questions, please do not hesitate to contact the Society of Plastics Industry. We are committed to working with the EPA in this important matter.

Sincerely,



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FMG Presentation to EPA April 26, 2002

Sanitized Copy

Three Blank Slides w/CBI Redacted

Company Sanitized

FMG

A Special Purpose Committee of the SPI

The mission of the FMG is to promote the continued safe manufacture & use of fluoropolymers made using fluorinated polymerization aids (FPA) while establishing & supporting responsible care in the use of fluoropolymer products & minimizing the impact on the environment.

Agenda

- ✓ Risk Assessment Approach
- ✓ APFO Environmental Distribution - Potential Exposure Routes
- ✓ Reductions in Environmental Releases - Industry Efforts
- ✓ Future Activity

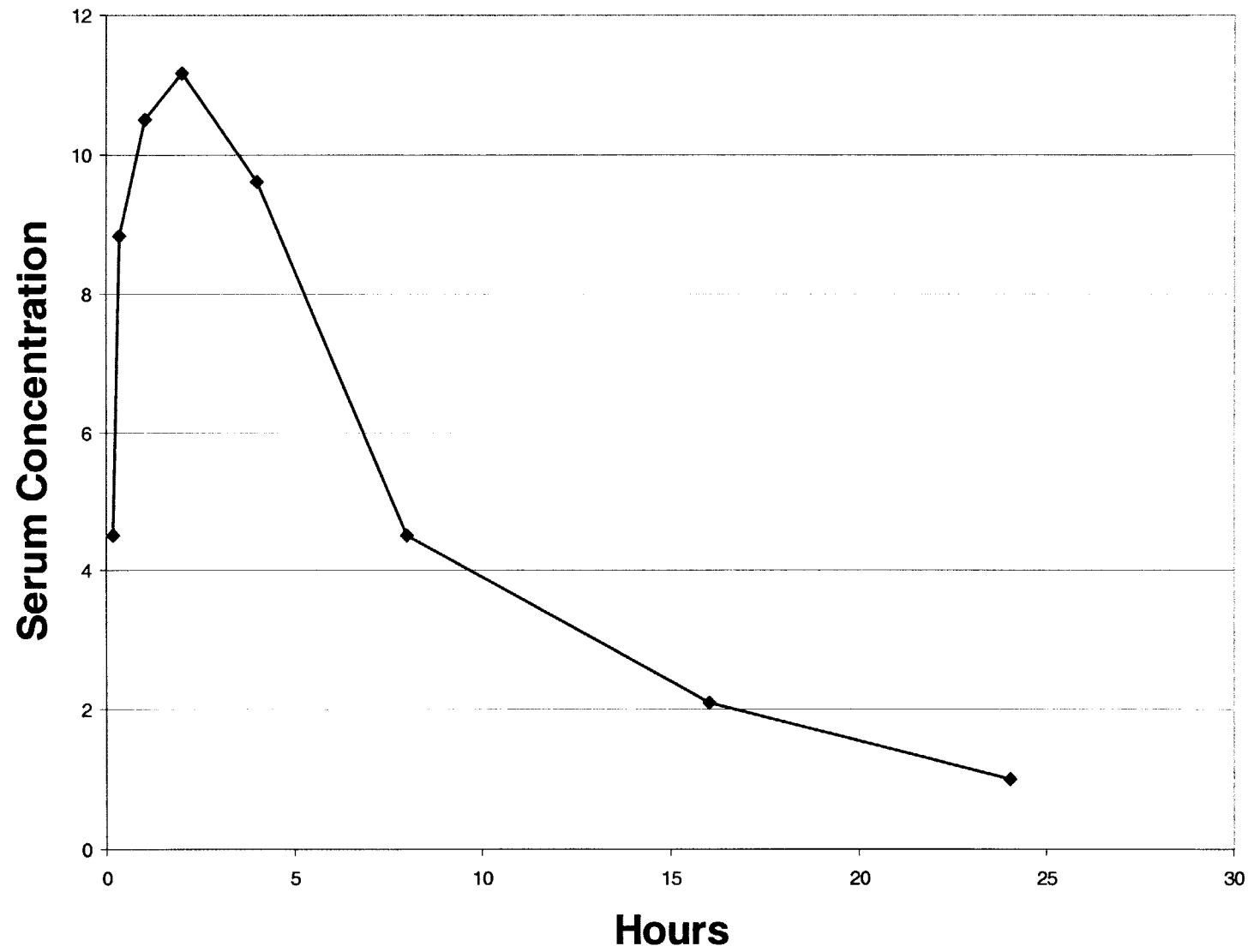
Question?

Are PFOA Serum Concentrations from Rat
Toxicological Studies Useful in Human-
Health Risk Characterization?

Relevant Facts in the Rat Model

- Serum PFOA does not correlate to cumulative dose in rats
- Female rats rapidly absorb and excrete PFOA such that the concentration in serum is dependent on time of sample relative to the time of last dose.

Illustrative Clearance Curve



Other Examples (Females)

- ✓ 100 % of an oral dose of ^{14}C -PFOA in pregnant rats was recovered in urine within two days.
- ✓ Female rats excreted essentially 100% of an i.v. dose of ^{14}C -PFOA after 24 hours.
- ✓ After single oral doses of 2.5 to 150 mg/kg PFOA to female rats, blood [PFOA] was 3 to 162 ppm at 30 minutes and 0.12 to 18 ppm at 24 hours.

Serum [PFOA] is not proportional
to dose in male rats (and
monkeys) after repeated oral
doses.

Examples (Males)

Mean male rat serum [PFOA] at the end of dosing for 106 days at 10 and 30 mg/kg/day were 50 and 45 ppm, respectively.

Mean serum concentrations in male cynomolgus monkeys after six months of dosing at 3, 10 and 30/20 mg/kg/day were 77, 86 and 158 ppm, respectively.

Answer

Serum [PFOA] in female (and male) rats after dosing is not a reliable indication of cumulative internal dose for use in human-health risk characterization.

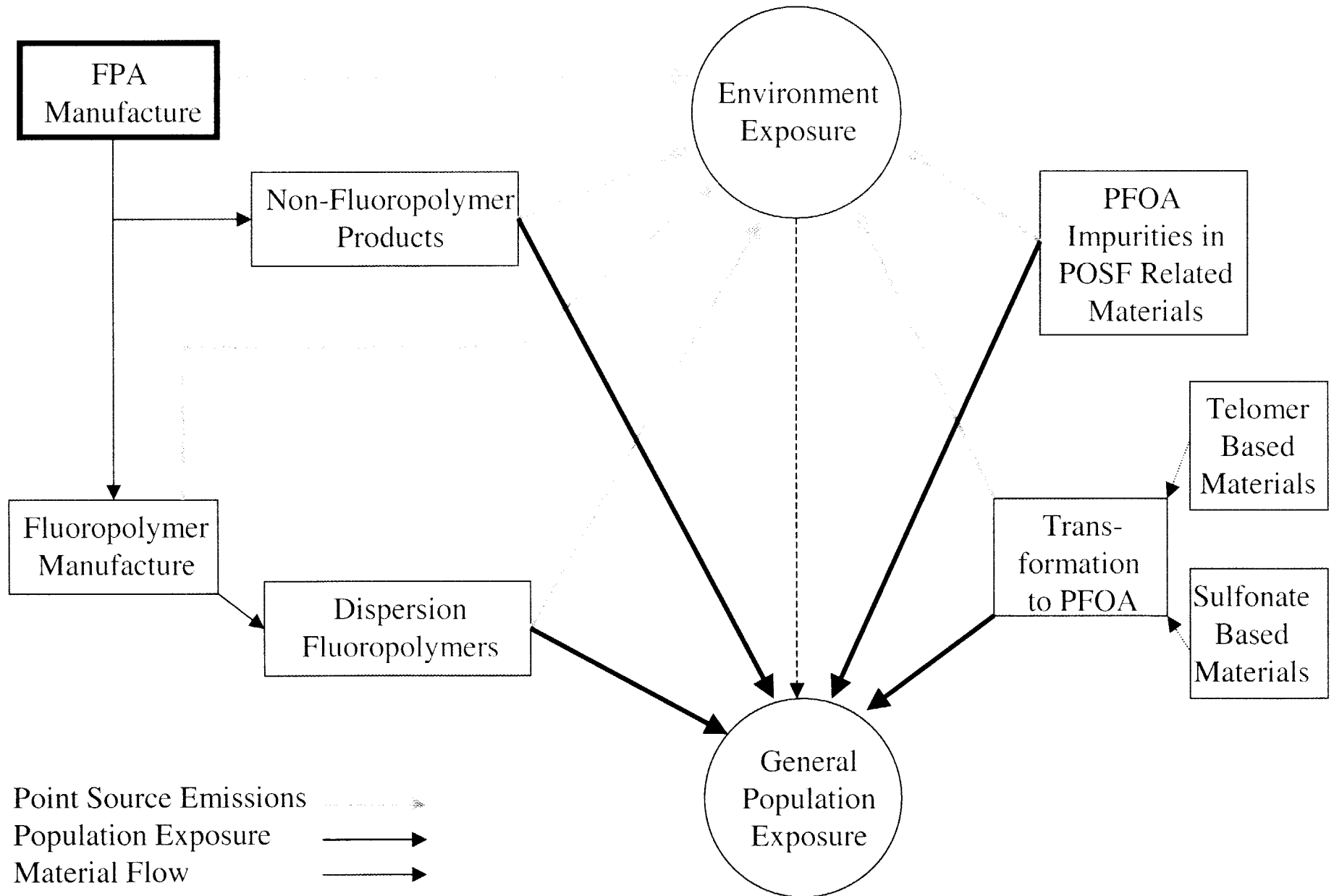
Recommendation

Use of standard EPA risk-characterization procedures, e.g., going from external dose in the animal model and application of appropriate uncertainty factors appears to be more appropriate for human-health risk characterization with PFOA.

Question?

- How is PFOA distributed to the US population? (Auer, 1/30/02)

Possible Sources of Exposure



FPA Manufacturing Point Source Emissions

New Capacity in US After 3M Phase Out

- Significant Reduction in Capacity/Production
- Significant Reduction in Emissions
- Significant Reduction in Alternative Uses

U.S. APFO Manufacturing Summary

✓ Significant Reduction in Capacity

- 3M Production 227 tonnes (500,000 lbs)/yr
- New US Capacity < 136 tonnes (300,000 lbs)/yr
 - 40% Reduction in Capacity vs. Actual 3M Production

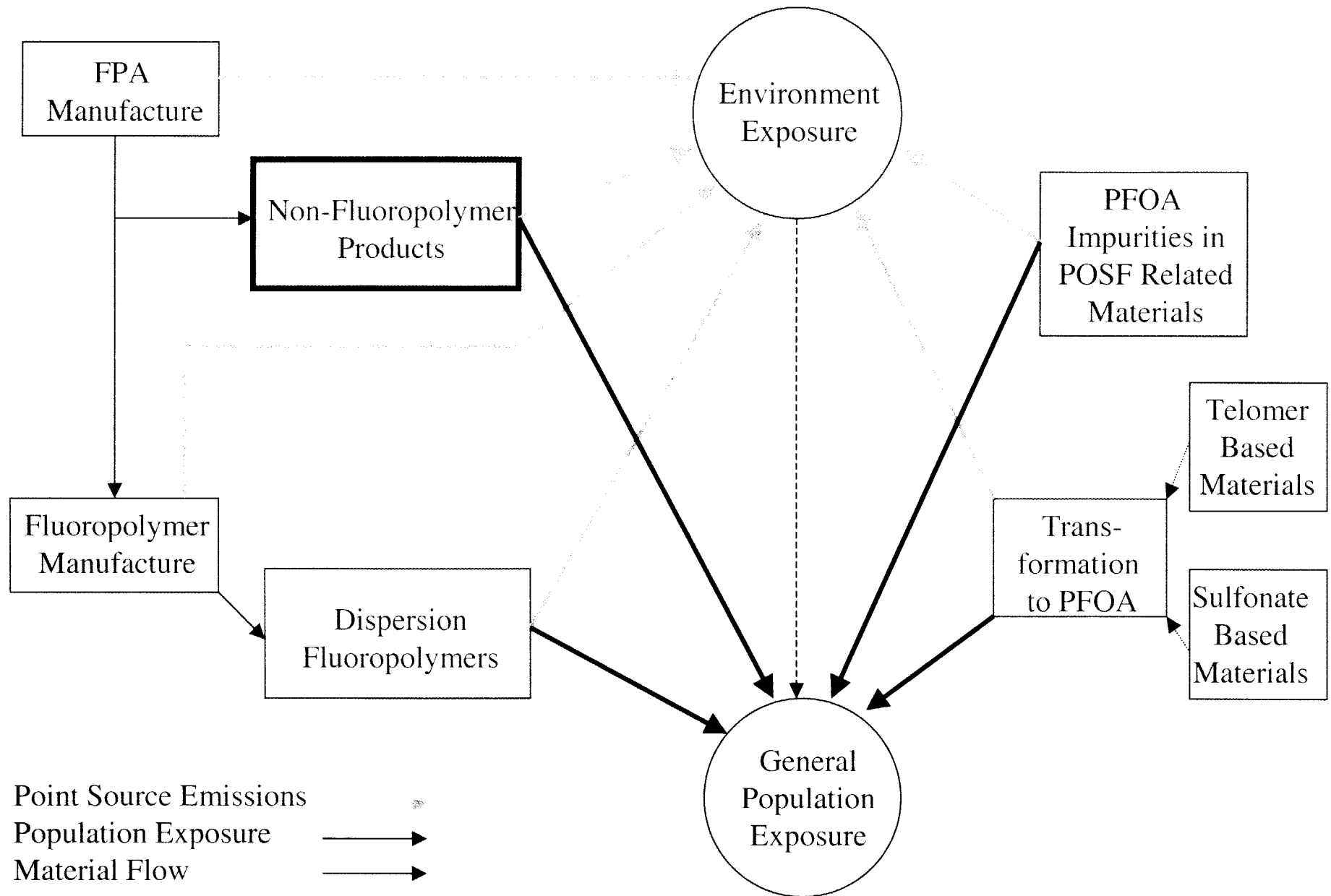
✓ Significant Reduction in Emissions

- 3M Emissions < 21 tonnes (46,950 lbs)/yr
- New US Capacity Emissions < 0.5 tonnes (1000 lbs)/yr
 - 98% Reduction

✓ Significant Reduction in Alternative Uses

- 3M non-Fluoropolymer industry global sales – 6 tonnes (12,500 lbs)/yr
- New US Capacity non-Fluoropolymer industry sales - Zero

Possible Sources of Exposure

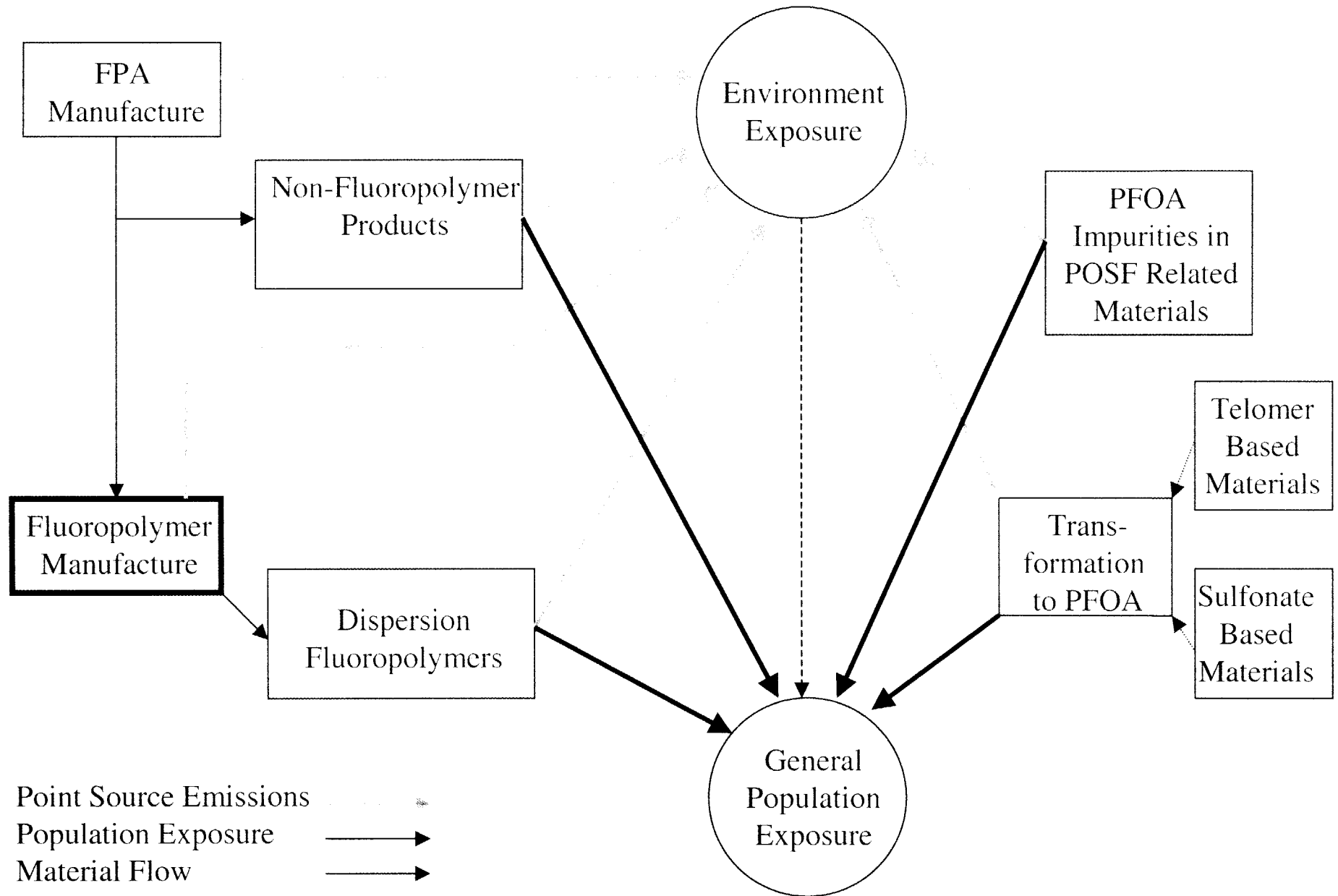


Non-Fluoropolymer Products

- 3M exiting production and marketing
- Dyneon will not market APFO
- Dupont and Daikin announced they will only sell APFO to “experienced and responsible users” in the Fluoropolymers industry.

6 tonnes (12,500 Lbs)/yr (3M global sales) -----> ZERO

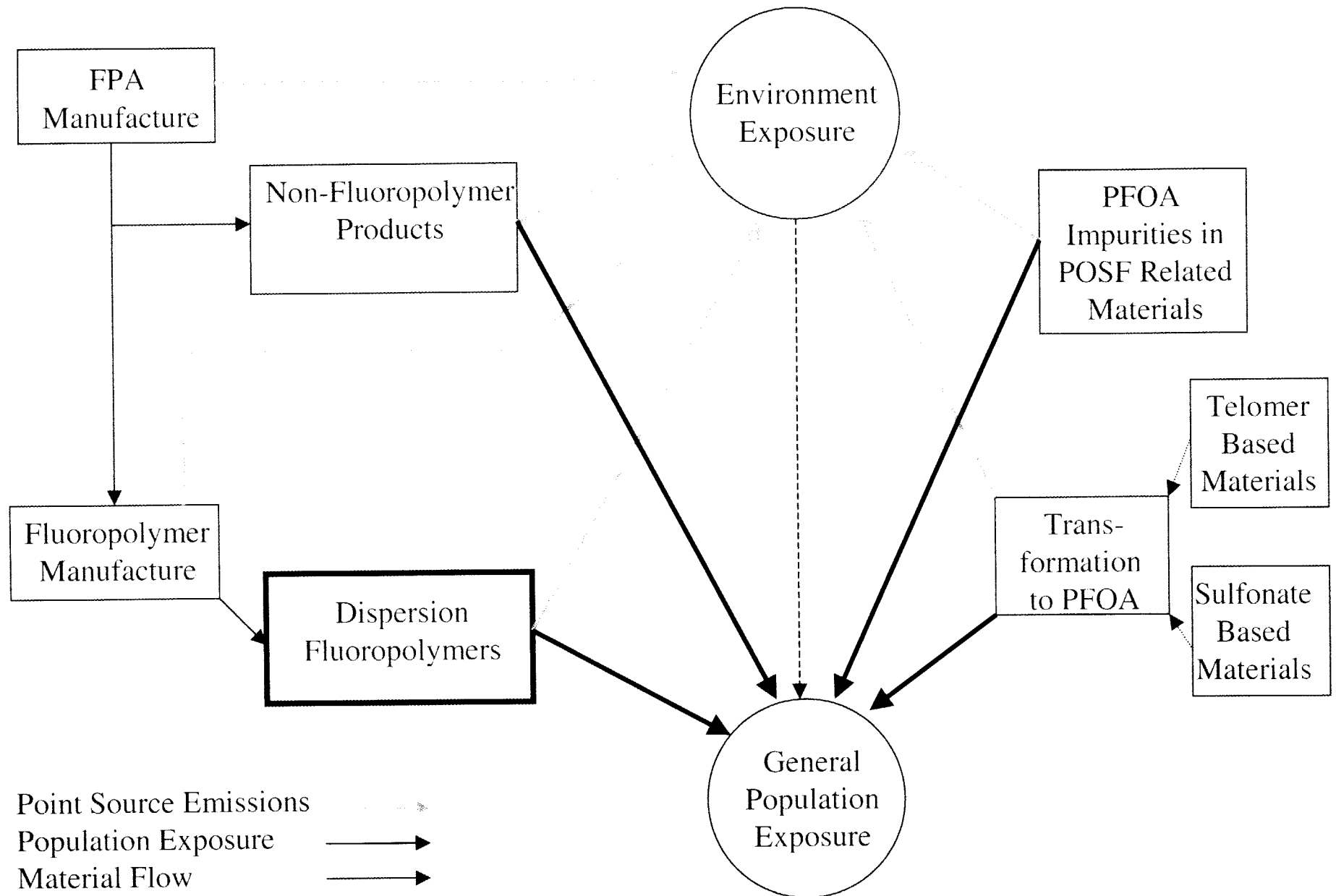
Possible Sources of Exposure



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Possible Sources of Exposure

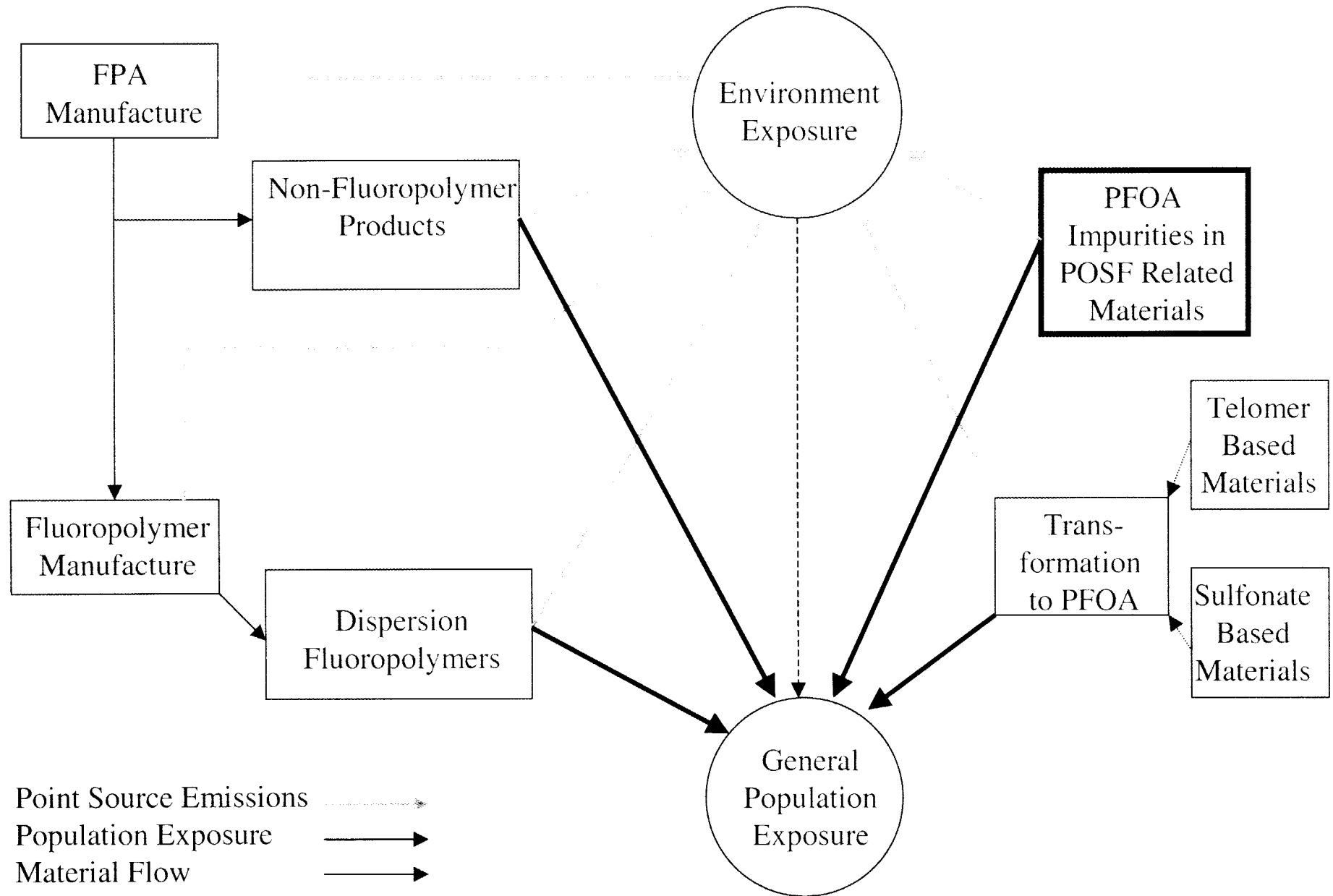


Dispersion Fluoropolymers

- ✓ Voluntary material balance request did not provide adequate information
- ✓ Will facilitate material balance
 - Developing communications package
 - Developing testing protocol
- ✓ Goal to complete material balance by December 2002

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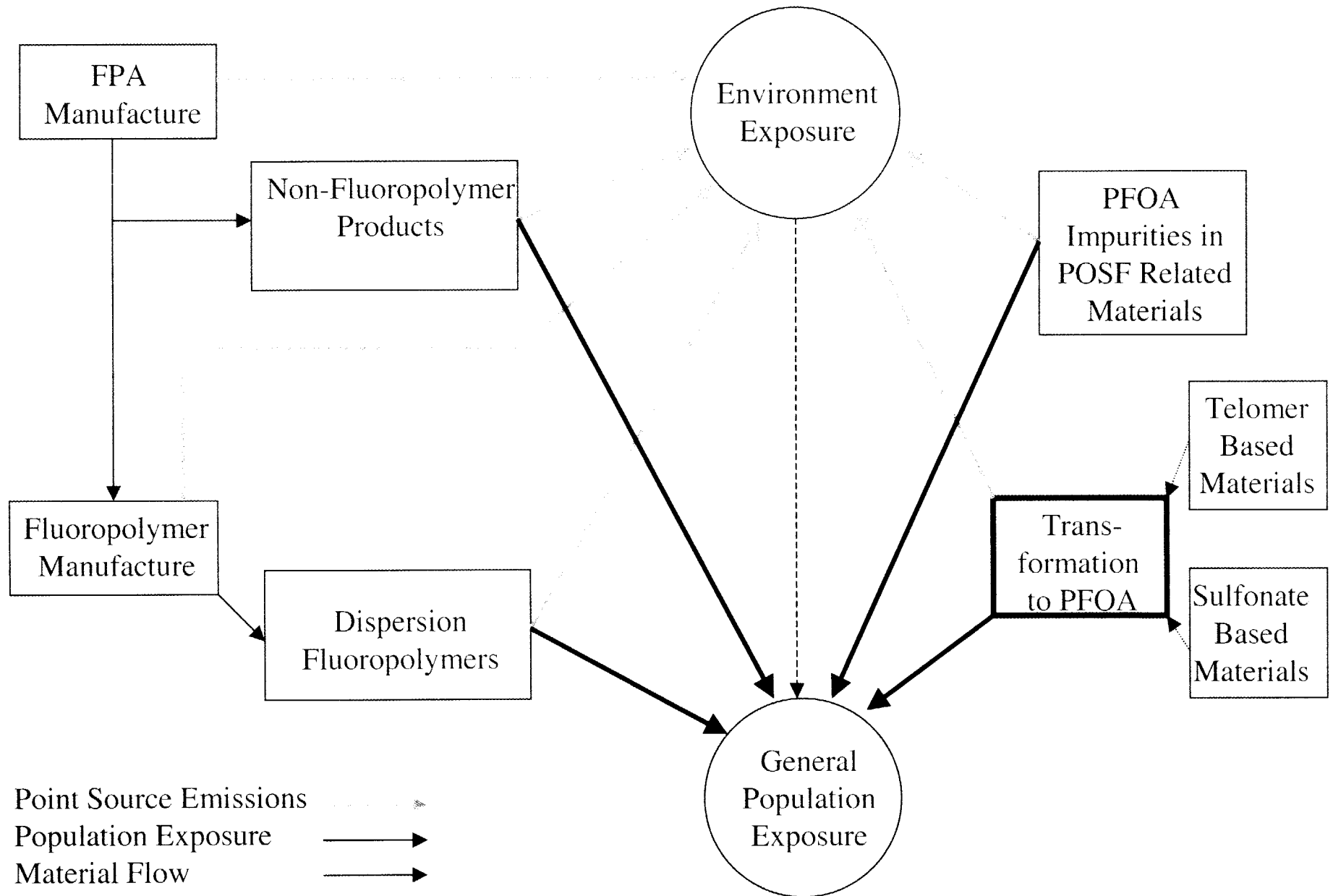
Possible Sources of Exposure



PFOA Impurities in POSF Related Materials

- ✓ Some POSF related products had PFOA impurities at low levels
- ✓ Recent 3M study shows correlation between PFOS and PFOA levels in human blood

Possible Sources of Exposure



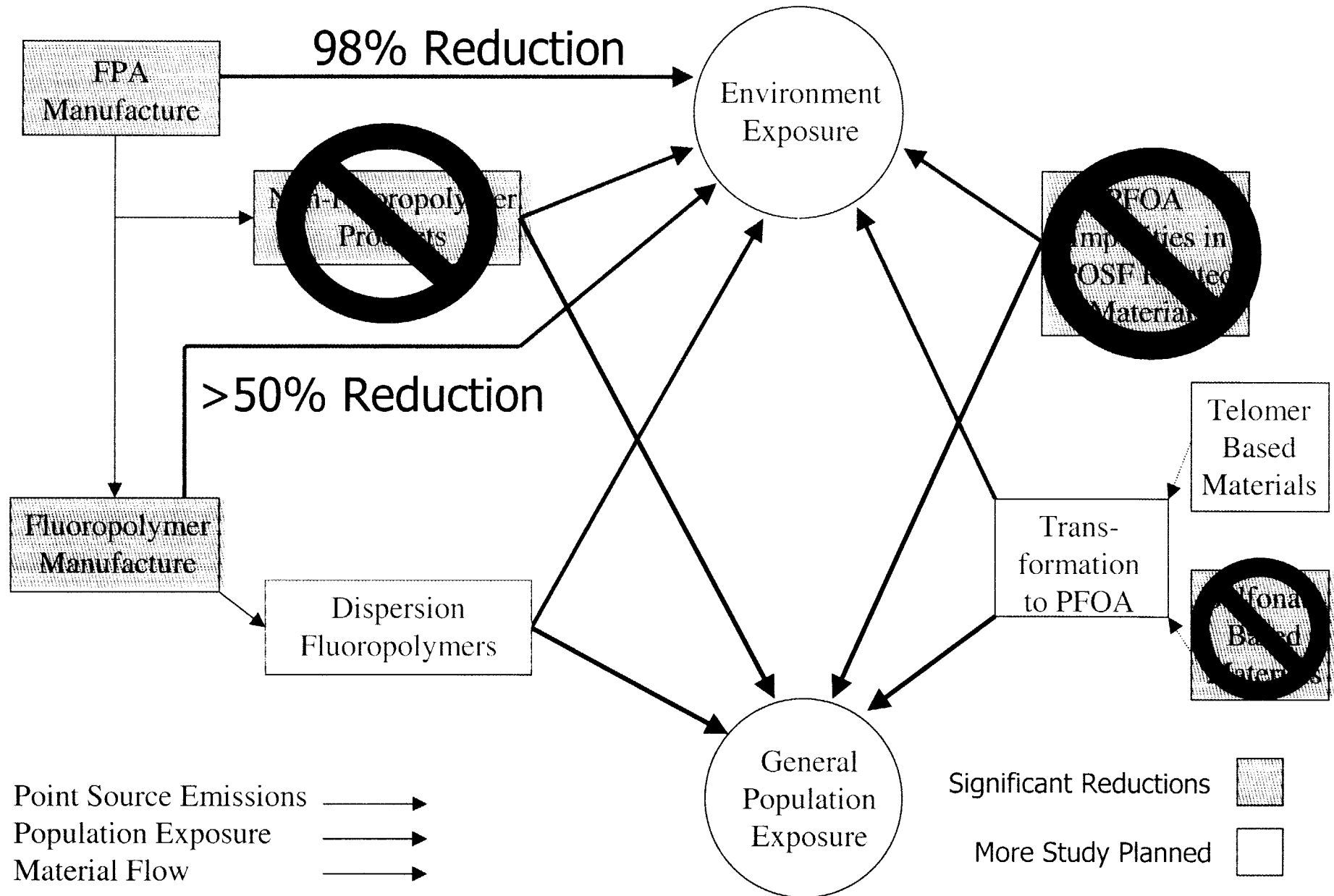
Potential Transformation to PFOA

Sulfonate based - 3M stops production

- 3M study shows perfluorosulfonamide derivatives may be transformed abiotically to PFOA

Telomer based - TRP plan previously communicated to EPA

Possible Sources of Exposure



Question?

How is PFOA distributed to the US population? (Auer, 1/30/02)

Future Activity

✓ Review and evaluate 3M U.S. population blood data

- Sampling
 - Distribution of samples
 - Procedures for obtaining samples
- Analytical procedures
 - Procedures specific for PFOA
 - Peer reviewed

Future Activity

- ✓ Assure appropriate sampling and appropriate and validated analytical procedures
- ✓ Continue to investigate the toxicology of APFO and the impact on the kinetic modeling
- ✓ Understand the potential for Telomer contribution

→ Evaluate the need to monitor blood

On-Going Activity

- ✓ Toxicity and Environmental Fate and Effect work to continue as planned
- ✓ Significant reduction in emissions and distribution from the fluoropolymer manufacturing industry
 - FMG to provide forecast for emissions reduction
 - FMG to provide periodic emissions summary
- ✓ Studies planned or scheduled for other potential contributors
 - FMG will facilitate dispersion processors material balance
 - TRP to communicate on Telomer issues

Summary

- ✓ Risk Assessment should continue via normal procedures
- ✓ No known adverse human health effects
- ✓ Significant reduction in potential exposure sources
 - emissions at fluoropolymer plants
 - emissions from new US FPA capacity
 - elimination of sales outside the fluoropolymer industry
 - phase out of POSF related materials
- ✓ Toxicity and Environmental Fate and Effect work continues on schedule