INTERNATIONAL IMAGING INDUSTRY ASSOCIATION
EUROPEAN PHOTO AND IMAGING ASSOCIATION
PHOTO-SENSITIZED MATERIALS MANUFACTURERS' ASSOCIATION

January 30, 2006

Via E-mail
Secretariat of the Stockholm Convention
Attn. POPs Review Committee
United Nations Environment Programme
11-13 chemin des Anemones
CH-1219, Chatelaine, Geneva, Switzerland

Re: Submission of Annex E Information on PFOS and Its Precursors

Dear Mr. Buccini:

On behalf of the International Imaging Industry Association (I3A), the European Photo and Imaging Association (EPIA), and the Photo-sensitized Materials Manufacturers' Association (PMMA)[1], I am pleased to provide this response to the November 18, 2005 request from the Stockholm POPs Review Committee (POPRC) for submissions of Annex E information on the use of Perfluorooctane Sulfonate (PFOS) and its precursors. PFOS-related substances play a critical role in manufacturing and product performance of both traditional and digital imaging. Voluntary efforts by our members to develop alternatives to PFOS have dramatically reduced the quantities used by our industry, and we believe that the emissions from our processes and products do not present a significant environmental or health concern.

This submission provides information on the use of PFOS and possible precursors by imaging industry members in critical manufacturing operations for traditional imaging products. For information related to PFOS uses in the manufacture of semiconductors for digital imaging equipment products, I would ask that you kindly refer to the submission provided jointly by the Semiconductor Industry Association, the European Semiconductor Industry, and the Semiconductor Equipment and Materials International.

Member companies of I3A, EPIA, and PMMA would appreciate the opportunity to continue dialogue with the Secretariat and POPRC on this very important issue, especially in the period leading up to the POPRC meeting on May 1-5, 2006 in Geneva.

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[1] I3A represents photo imaging companies from around the world, EPIA represents photo imaging companies and European national associations of photo imaging companies, and the PMMA represents photo imaging companies in Japan. Member companies include the major manufacturers of photographic products; Agfa, Eastman Kodak Company, Fuji Photo Film, Konica Minolta, and Kodak Polychrome Graphics.

PFOS Uses by the Photo Imaging Industry

The photo imaging industry uses PFOS chemicals in the manufacture of a variety of sensitized photographic products. Chemicals of this class provide antistatic, surfactant, friction control, and dirt repellant qualities. With the development of materials that are more sensitive to light (i.e., faster film speeds, more sensitive diagnostic X-ray products) and the growth of digital products that are processed dry, these properties have become even more important and require the use of perfluorinated coating aids.

The PFOS materials not only provide performance features necessary for the manufacture and use of imaging products, they also provide important safety features by controlling the build-up and discharge of static electricity. The antistatic properties of these materials are important for preventing employee injury, operating equipment and product damage, and fire and explosion hazards. Only very small quantities of PFOS materials are required to function as coating aids in imaging media, since thinner coatings make clearer, sharper images. Typical coating concentrations for film range from 0.1 to 0.8 $\mu g/cm^2$.

Alternatives to PFOS in the Photo Imaging Industry

Member companies do not use PFOS itself, and have conducted extensive research into alternatives to PFOS-related substances, reducing their use markedly since 2000. While many applications of PFOS substances have been eliminated, a small number of critical uses remain. According to an estimate developed by the United Kingdom Department for Environment, Food and Rural Affairs (Defra)[2], this accounts for less than 0.2% of the total use in the European Union. In addition, member companies have taken many steps to eliminate release of and exposure to the remaining PFOS-related substances. Based upon this combination of factors, we do not believe that the continuing critical uses of these substances by our industry are hazardous or present a significant risk to the environment.

In order for PFOS alternatives to meet the technical specifications for use in products, they must provide equivalent properties to PFOS. PFOS coating aids have a combination of surface-active properties that are not found with any other single class of chemicals. PFOS materials:

1. Lack photoactivity, and thus do not interfere with the imaging process
2. Promote uniformity of photoprocessing results by controlling surface wetting properties
3. Control splicing tape adhesion properties
4. Are compatible with photo-retouching materials
5. Improve camera, projector, and printer transport to eliminate unwanted photographic effects, and
6. Prevent the build-up of particles that can clog magnetic strip readers.

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[2] "Environmental Risk Evaluation Report: Perfluorooctanesulphonate". Environment Agency for England and Wales. September 2004.

The ability to control surface tension in imaging materials is a critical aspect of the use of PFOS materials as coating aids. In order to function, imaging materials may be coated with up to 18 layers of light sensitive materials at high speed to prevent drying of materials as they are applied. PFOS materials play a key role in minimizing manufacturing waste by contributing to the technology for creating coatings of high complexity in a highly consistent manner. The coating aid must allow the rapid uniform spreading of the layers so that irregularities in the coatings are avoided. Any irregularity in coating thickness makes imaging materials useless and increases manufacturing waste significantly. Coating aids must not be photoactive; otherwise, unacceptable fogging or speed effects may occur in the coatings.

PFOS coating aids also have unique properties at low concentrations for controlling static charge during the manufacture and use of imaging materials. This is particularly important for imaging materials that have a high sensitivity to light (i.e., high speed), as these products are unusually sensitive to light produced by static discharge during transport of imaging materials. Excessive friction during the transport of imaging materials and contamination of imaging materials by dirt or clogging of magnetic strip readers with debris can lead to significant waste of imaging materials during manufacturing and use.

Adhesion control is a property imparted to film coatings as a result of the use of PFOS materials as coating aids. Control of adhesion of various tapes to imaging materials is important because tape is the primary way in which imaging materials are attached to spools and to each other during processing. The strength of the bond between the tape and the imaging materials must be controlled so that imaging devices (e.g., cameras, photoprocessors) and imaging materials are not damaged during transport (i.e., the adhesive bond between the tape and the imaging material must be broken by a force that will not damage devices or materials being transported).

Since the announcement by the 3M Company in 2000 of its intention to discontinue manufacture of many PFOS chemicals, our industry has aggressively pursued a voluntary risk reduction strategy by investing heavily in research to find alternative substances that possess the properties described earlier for PFOS. Only a small number of critical PFOS applications remain.

Remaining Uses of PFOS in the Photo Imaging Industry

In 2005, our members conducted a survey of the volumes of PFOS used in the years 2000 and 2004. The data confirmed our earlier estimates that the use of PFOS chemicals in manufacturing and products has decreased considerably, by an average of about 70% in the European Union (EU) and 60% worldwide (Figure 1). Additional decreases in use are anticipated as the industry continues to transition towards digital imaging technologies.

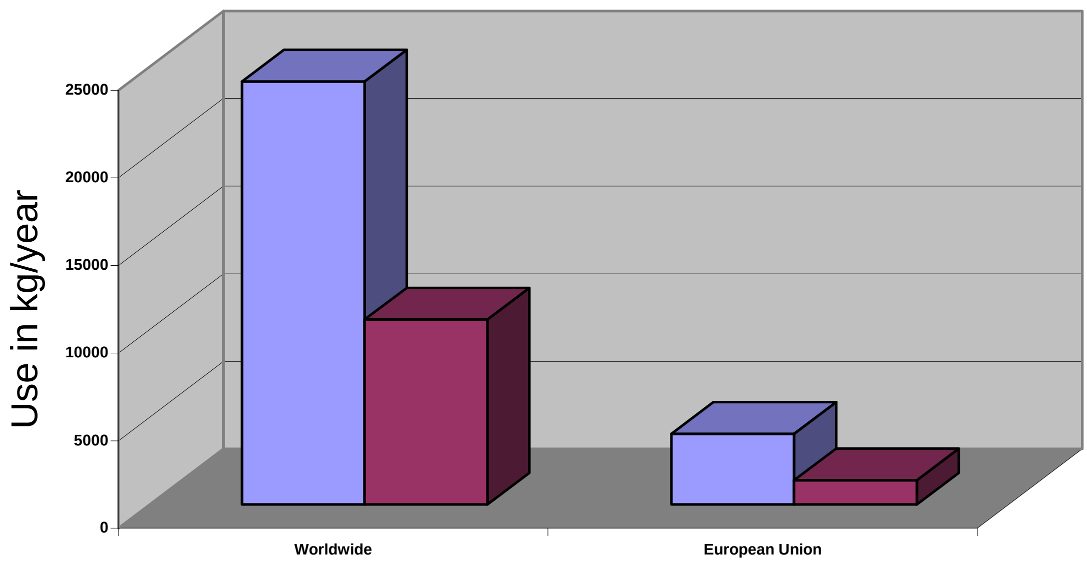

Figure 1: Uses of PFOS Substances by the Photo Imaging Industry in 2000 [■] and 2004 [■]. Survey conducted in 2005 by the Photo Imaging Industry.

A ban on the production of PFOS chemicals or a restriction on their use would have a severe impact on the photo imaging industry's ability to manufacture a number of imaging products. Such restrictions would impose a significant financial burden by requiring substantial investment in research and development during a time when the imaging industry is focused on the invention of innovative new digital imaging technologies.

Risks Associated with PFOS Use by the Photo Imaging Industry

The European Commission Scientific Committee on Health and Environmental Risks (SCHER) reviewed the Defra report[3] entitled *"Perfluorooctane Sulphonates: Risk Reduction Strategy and Analysis of Advantages and Drawbacks"* and estimated PFOS emissions in the EU[4]. Releases into the environment in 2002 from photographic product manufacture and processing were reported to be less than 8 kg/year. Of this 8 kg, however, 6.75 kg arises from an estimate made by the UK Environment Agency in its Risk Evaluation Report[2] and is not supported by data. The RER assumes that all PFOS materials are release from photographic products during processing. In fact, many of these products use PFOS-based polymers that would be expected to remain with the processed product. Further, the RER overlooks the fact that used photographic processing solutions are classified as hazardous waste that must be handled to avoid release to the environment. This erroneous assumption has a significant impact on the

[3] "Perfluorooctane Sulphonate: Risk Reduction and Analysis of Advantages and Drawbacks," UK Department of Environment, Food and Rural Affairs. August 2004.
[4] "Opinion on RPA's report "Perfluorooctane Sulphonates: Risk reduction strtategy and analysis of advantages and drawbacks,"" Scientific Committee on Health and Environmental Risks, European Commission. August 2004.

estimated environmental releases and the subsequent risk estimates. Without this contribution, estimated releases (water and air combined) amount to approximately 1.1 kg for the EU and <2 kg worldwide. Even with this greatly inflated emissions estimate from the RER, the SCHER determined that emissions in the EU of PFOS and PFOS-related substances from uses in the photographic industry amounted to less than 0.08% of the total EU emissions.

SCHER further concluded that:

> **"The contribution of the confirmed on-going industrial/professional uses to the overall risks for the environment and for the general public are probably negligible with regard to the sectors photographic industry, semiconductor industry, and aviation industry."**

In the USA, the Environmental Protection Agency in 2002 recognized several critical uses of these substances in the photo imaging industry and has allowed in the Agency's Significant New Use Rule[5] the continued manufacture, import, and use of specific PFOS chemicals for these applications.

Similarly, the proposed *Directive Relating to Restrictions on the Marketing and Use of Perfluorooctane Sulfonate* presented by the European Commission on December 5 2005, recognizes the assessment of SCHER that:

> **"… on-going critical uses in the aviation industry, the semiconductor industry, and the photographic industry do not appear to pose a relevant risk to the environment or human health, if releases into the environment and workplace are minimized."**

The Commission recommends derogations for ongoing PFOS uses by these industries[6].

Conclusion

The Photo Imaging Industry has a small number of on-going critical uses of PFOS substances. These chemicals impart unique properties during the manufacture, use, and processing of certain photographic products. The industry has reformulated or discontinued a large number of products, resulting in a more than 60% reduction in PFOS use worldwide between 2000 and 2004. Although replacements do not currently exist for the remaining critical product applications, further reductions in PFOS use are anticipated as the transition continues towards digital imaging technologies.

Accordingly, the photo imaging industry respectfully urges POPRC to provide a specific exemption from restrictions for production and use of PFOS by the photo imaging industry. Any production ban or restriction on the use of PFOS would have the effect of

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[5] "Perfluoroalkyl Sulfonates: Significant New Use Rule," United States Environmental Protection Agency, 40 CFR 721. December 2002.

[6] "Proposal For A Directive Of The European Parliament And Of The Council Relating To Restrictions On The Marketing And Use Of Perfluorooctane Sulfonates", (amendment of Council Directive 76/769/EEC). 12/5/05.

prohibiting the manufacture of these critical imaging products, without accomplishing any significant benefit to the environment or human health. Regulatory agencies from the USA, UK, and EU have concurred that the remaining uses of PFOS by the imaging industry do not present a significant risk to human health or the environment.

The attached Annex E submission provides additional information for consideration by POPRC.

We appreciate the opportunity to respond to the Secretariat's request for information on PFOS and look forward to additional dialogue on this important issue for our industry.

If you have any questions about these comments, please do not hesitate to contact me.

Sincerely,

Derek Guest

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Format for submitting pursuant to Article 8 of the Stockholm Convention the information specified in Annex E of the Convention

Introductory information	
Name of the submitting Party/observer	International Imaging Industry Association, European Photo and Imaging Association, and Photo-sensitized Materials Manufacturers' Association (major member companies Agfa, Eastman Kodak Company, Fuji Photo Film, Konica Minolta, and Kodak Polychrome Graphics).
Contact details (name, telephone, e-mail) of the submitting Party/observer	Dr. Derek Guest (Eastman Kodak Company) Tel: + (1 585) 722-3949 E-mail: derek.guest@kodak.com
Chemical name (as used by the POPS Review Committee (POPRC))	PFOS
Date of submission	January 30, 2006

(a) Sources, including as appropriate (provide summary information and relevant references)	
(i) Production data:	
Quantity	Less than 10,000 kg/year used worldwide in 2004 for photographic films, papers, and printing plates. This is a reduction over 60% from the 25,000 kg/year in 2000.
Location	Predominantly USA, Japan, EU, China
Other	Uses in photographic developing solutions discontinued.
(ii) Uses	Antistatic; surfactant; friction control; dirt repellant; semiconductor photolithography.
(iii) Releases:	
Discharges	To water, estimated to be approx. 1.6 kg/year worldwide.
Losses	
Emissions	To air, estimated to be approx. 0.1 kg/year worldwide. Combined air and water estimated to be less than. 2 kg/year worldwide.
Other	The release of PFOS from PFOS-related substances related to photographic uses has been incorrectly estimated in the UK Environment Agency Risk Evaluation Report (RER). Although fluorochemical residuals may be present in small quantities in PFOS polymeric materials, there are no data to suggest the presence of free PFOS in the polymers. The RER estimate the release of PFOS from film development by assuming complete release of PFOS content, a wholly unreasonable assumption. Further, the RER overlooks the fact that used photographic processing solutions are classified as hazardous waste and must be handled in a manner that prevents release to the environment. Instead, the RER assumes that all photographic waste enters the environment untreated; an assumption that is not warranted and one that has a significant impact on the resulting risk estimates. Thus the annual estimated release worldwide would amount to approximately 2 kg. *Reference* "Environmental Risk Evaluation Report: Perfluorooctanesulphonate". Environment Agency for England and Wales. September 2004

(b) Hazard assessment for endpoints of concern, including consideration of toxicological interactions involving multiple chemicals (provide summary information and relevant references)

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In striving to develop a toxicity classification for PFOS based on mammalian toxicity data, the UK RER overlooks fundamental differences between aquatic and mammalian organisms that bring into question the appropriateness of the toxicity classification. Due to differences in physical characteristics and the extent of absorption, toxicity data generated in laboratory animals are not appropriate for classifying PFOS for secondary poisoning in the aquatic environment. PFOS exists normally as a weak acid whose degree of ionization is controlled by the pH of the surrounding environment. At the nearly neutral pH of freshwater and marine environments, PFOS will be found in an ionized state because the commonly found salt forms will dissociate in solution.

In reviewing the RER, the European Commission's Scientific Committee on Health and Environmental Risks concluded that:

> **"The contribution of the confirmed on-going industrial/professional uses to the overall risks for the environment and for the general public are *[sic]* probably negligible with regard to the sectors photographic industry, semiconductor industry, and aviation industry" (emphasis provided).**

Similarly, in the proposed "Directive Relating to Restrictions on the Marketing and Use of Perfluorooctane Sulfonates" the European Commission acknowledges that:

> **"… on-going critical uses in the aviation industry, the semiconductor industry, and the photographic industry do not appear to pose a relevant risk to the environment or human health, if releases into the environment and workplace are minimized" (emphasis provided).**

In the USA, the Environmental Protection Agency in 2002 recognized several critical uses of these substances in the photo imaging industry and has allowed in the Agency's Significant New Use Rule the continued manufacture, import, and use of specific PFOS chemicals for these applications.

References

"Opinion on RPA's report "Perfluorooctane Sulphonates: Risk reduction strtategy and analysis of advantages and drawbacks,"" Scientific Committee on Health and Environmental Risks, European Commission. August 2004

"Proposal For A Directive Of The European Parliament And Of The Council Relating To Restrictions On The Marketing And Use Of Perfluorooctane Sulfonates", (amendment of Council Directive 76/769/EEC). 12/5/05

"Perfluoroalkyl Sulfonates: Significant New Use Rule," United States Environmental Protection Agency, 40 CFR 721. December 2002

(c) Environmental fate (provide summary information and relevant references)	
Chemical/physical properties	
Persistence	
How are chemical/physical properties and persistence linked to environmental transport, transfer within and between environmental compartments, degradation and transformation to other chemicals?	
Bio-concentration or bio-accumulation factor, based on measured values (unless monitoring data are judged to meet this need)	**In striving to develop a toxicity classification for PFOS based on mammalian toxicity data, the RER overlooks fundamental differences between aquatic and mammalian organisms that bring into question the appropriateness of the toxicity classification. Due to differences in physical characteristics and the extent of absorption, toxicity data generated in laboratory animals are not appropriate for classifying PFOS for secondary poisoning in the aquatic environment. PFOS exists normally as a weak acid whose degree of ionization is controlled by the pH of the surrounding environment. At the nearly neutral pH of freshwater and marine environments, PFOS will be found in an ionized state because the commonly found salt forms will dissociate in solution.**

(d) Monitoring data (provide summary information and relevant references)

Occupational Monitoring

Occupational exposure to PFOS chemicals in the Photo Imaging Industry is expected to be minimal. Many of the PFOS chemicals used are polymeric materials of relatively large molecular weight or are controlled in the workplace because of their solvent content (toluene, ethyl acetate, methyl ethyl ketone, and isopropyl alcohol). When coating formulations are prepared, employees are required to wear uniforms, eye shields, and gloves, and sometimes respirators. The diluted PFOS-containing mixtures are transferred using automatic piping from the mix preparation area to the production area where they are added to coating machines that handle the actual application of the coating mixtures with only minimal human intervention since coating must be conducted in a clean environment. Employees are generally not allowed in the coating rooms during coating and drying operations. Even for employees addressing mechanical failures, exposure is expected to be zero to minimal as the PFOS materials are bound in coating media and may have a surface overcoat.

Photo imaging industry members conducted monitoring for occupational exposure in four different workplaces where PFOS products were handled and mixed. At the workplaces, there was no opportunity for ingestion of or dermal or ocular contact with the PFOS materials as protective gloves, goggles, and eye shields were routinely in use. Airborne concentrations of residual fluorochemicals were measured using personal and area monitoring while dispensing and mixing four different PFOS products. In all cases, the results show that airborne concentrations in the workplace were below detectable levels (< 0.013 mg/m^3).

(e) Exposure in local areas (provide summary information and relevant references)	
- general	
- as a result of long-range environmental transport **- information regarding bio-availability**	

(f) National and international risk evaluations, assessments or profiles and labelling information and hazard classifications, as available (provide summary information and relevant references)
The UK RER uses data from a rat cancer bioassay to calculate risk ratios (PEC/PNEC) , presumably because there were no data available indicating that wildlife species are adversely affected by PFOS. **The RER cites PEC/PNEC ratios for secondary poisoning from freshwater release that range from 24-41 fold for photographic uses. The PNEC used to determine the excess risk from bioconcentration and biomagnification in the food chain was derived from an evaluation of the toxicity to male rats exposed to PFOS in the diet for two-years. In this study, when the dietary dose was increased 10-fold from the NOEL of 0.5 ppm to a level of 5 ppm, distinct macroscopic changes occurred in the liver. These gross pathological changes, including mottling and enlargement, have not been reported in birds, mink or any other fish-feeding animal that would be susceptible to the secondary effects. The predicted minimum 24-fold increase in risk resulting from current PFOS use patterns would certainly have caused a noticeable change in species diversity and population dynamics due to excess mortality in the affected animals. The cause of this discrepancy may lie in pharmacokinetic differences between rats and aquatic feeding animals. Rats exposed at a nontoxic level of 0.5 ppm for two years had an average PFOS concentration in the liver of 7.8 µg/g (a 5 ppm hepatotoxic dose caused average liver concentrations of 70.5 µg/g). Yet birds, bears, otters, and other higher trophic animal species have never been found to have liver PFOS levels in excess of 5.1 µg/g, and the average concentrations have typically been less than 1 µg/g. If the current risk assessment is correct for secondary poisoning, then it is reasonable to assume that liver levels in some animals should be in excess of 185 µg/g (24 x 7.8). Since this is not the case for the aquatic-feeding animals of interest, it suggests that rats and other rodents may be clearing PFOS more slowly following absorption and that the dosimetry is distinctly different for the two classes of animals.** **A specific biologic difference between rats and other higher trophic species (such as birds and fishes) that has not been taken into account in the risk assessment is the testosterone-regulated renal transport of perfluorinated fatty acids reported by Kudo *et al*. (2002). Reduced PFOS renal clearance in male rats may account for the greater toxicity of PFOS in male rats versus female rats and the much higher blood levels that have been reported in male rats compared to other species.** ***Reference*** **N. Kudo, M. Katakura, Y. Sato, and Y. Kawashima (2002). Sex hormone-regulated renal transport of perfluorooctanoic acid. Chemico-Biol. Interact. 139, 301-316.**

(g) Status of the chemical under international conventions