

**Plastics Europe Fluoropolymers Committee**  
**Environmental, Toxicology & Science Working Group**

**Minutes Inaugural Meeting**

**11<sup>th</sup> March 2009, Brussels**

**Drafted: 15 Mar 2009**

**Participants**

W de Wolf (DuPont) Chairman, D Farrar (Ineos Chlor - for Asahi Glass Chemicals Europe), I Gaou (Arkema), G. Radau (Daikin), R Jung (Clariant - for Dyneon), W Braes (W L Gore), J Franklin (Solvay), M Neal – *PlasticsEurope*

**By phone**

F. Morandi (Solvay Solexis), I Colombo (Solvay Solexis), E Lampert, (Lampert & Associates -for Daikin till 11 am), G Kennedy (DuPont, Haskell Global Centers, from 11:30 am), J Butenhoff (3M, from 1:30 pm)

**Apologies or no reply**

W Fischer (Ciba), M Santoro (3M), M Henegan (Ciba), D Boothe (DuPont),  
D Drusian(Miteni), G Kaempf (Dyneon), S Chang (3M), S Shin-ya (Asahi Glass), H  
Iwai (Daikin), C Elcombe (CXR Biosciences), G Costa (University of Milan - for  
Miteni), B Schmit (Solvay), G Malinverno (Solvay), B Kiehl (W L Gore), L Hoy (Asahi  
Glass), E Van Wely (DuPont), P Hoff (3M), G Andrews (AGCCE),

**Welcome, Introductions, Agenda review**

W de Wolf welcomed all to the inaugural meeting of the newly formed Environmental, Toxicology and Science Group (ETS).

The agenda was approved.

**Adoption of Ad hoc Tox working group and FAS group minutes January 2009 (27 & 28<sup>th</sup> respectively)**

M Neal to change the name on the last set of ad hoc tox group minutes (from ETS to ad hoc tox). The minutes were then approved.

**Matters Arising – Ad hoc Tox**

The German RA will become available after a meeting on 12<sup>th</sup> March in case agreement with the authorities can be reached on the path forward.

IARC – still outstanding

**Action** – G Kennedy to send EPA agenda

**Action** – Create an action list at the bottom of each set of minutes

**Action** – Check with G Malinverno re the GHS/SIG action

**Action** – W de Wolf to circulate the Risk Assessment when available.

**Action** – D G Farrar to monitor – continues from last meeting

**Action** – I Gaou to provide M Neal with C9's table for circulation.

**Action** – M Neal to create a paper archive for the group.

### **FAS minutes**

**Action** – M Neal to send these minutes to the former FAS group for their approval.

**Action** - Monitoring activity on Perforce 3 still to be discussed J Franklin, P de Voogt & W de Wolf.

### **Fluoropolymer Main Committee suggested remit**

There was a discussion on the proposed remit of the group (.ppt file on the extranet) The Management committee had made a suggestion but asked the group to agree and build the remit further. A suggestion was made that we should first review the science and then revise the remit in light of the outcome. The revised remit could then be presented to the Management Committee on May 20<sup>th</sup>.

After a short discussion there was agreement that the group is a reactive group, in the sense that it is looking at health and environmental issues on substances of interest proposed by the Management Committee. However, the Management Committee needs to understand and be made aware of other science issues too i.e. epidemiology etc. Hence, there is a degree of freedom for the group to identify issues upwards so that the Management committee can agree that ETS will handle them. With PFOA we need to monitor new science developments and assess the impact of these on the industry.

### **Remit & Work programme for ETS**

#### **Introduction company inputs**

We do need to get the support of the Management Committee for a work programme we propose within the remit.

W L Gore provided an input on their views as to how the ETS should move forward and where it is likely to be in 5 years time (see Appendix 1). The group is in a unique situation as it includes both manufacturers and down-stream users. AGCCE supplied comments and they are in appendix 2, Solvay provided written comments (See appendix 3) and a presentation by I. Colombo to introduce the comments (on extranet). Dyneon suggested that we should follow (inter)national attitudes of regulators towards PFCs. Also, we should help regulators and academics to understand that perfluorinated substances cannot be considered all the same. There are many differences as well as some similarities.

Taking this into consideration, it was suggested we look at a potential work programme structured along the headings: Polymers, monomers & processing aids.

**Action** - M Neal to check the future Miteni participation in the group

**Action** – M Neal - can W L Gore attend the Management Committee meeting and if so in what capacity?

### **General discussion**

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specific additional company experts where needed) which report back into the Working Group according to agreed timelines and priorities. In the current financial crisis, we should avoid funding research as much as possible, and use our networks and stick to literature reviews in the short term. It was recognized that we have to manage the work programme using sweat equity in the group, although there will be a need for focused or specialised expertise for some issues and this will require the Management Committee to spend money. Additionally there may be a need for new data and this also requires funding.

## Polymers

When considering the lifecycle of the polymer, what information do we have available, and is there a need for further information?

Is there evidence which contradicts the industry understanding that there is no inherent harm of polymers for the environment? None of the participants is aware of any. Maybury produced a paper on decomposition and formation of trichloroacetic acid and long chain perfluorocarboxylic acids with low yield (note: in this context PFOA is considered a long chain acid). J Franklin wrote a critique on this paper. Overall there is a lot of data on oxidative pyrolysis of FP's but none suggestive of inherent harm for the environment.

Many of the issues reported on FP are a result of misuse of FP's, or flawed experiments. For instance, there was a paper published by Kannan on the overheating of cookware producing FTOH's and PFOA? This is not possible.

Oxidative pyrolysis is not an ongoing research issue. Health impact was dealt with years ago. Pyrolysis of FP's may give rise to polymer fume fever. Also with other polymers and metals fume fevers do occur. Is there a common mode of action e.g. do combustion products include nano particles?

The formation of higher homologues could become an issue. It is suggested the Working Group keeps a watching brief on fluoropolymer decomposition research.

Some information is available on polymer incineration studies (>800 degr. C) but limited data exist on its fate in landfills.

We should review whether the PlasticsEurope fluoropolymer safe handling guide (updated by other PE-groups Sept 2008) reflects the current state of the environmental and toxicological science and the BAM work.

**Action** – W de Wolf, Make this an agenda item for next meeting.

## Monomers

### TFE Epidemiology Study

A subset of ETS members (e.g. David Farrar, Ikarria Colombo, Reinhard Jung) has been involved in a retrospective mortality study with IOM, Rome. Tumours and tumour location will be assessed on a multicenter analysis basis. The study was delayed due to missing data, but a draft report is expected shortly. A meeting to discuss the draft is considered for June/July.. One of the consultant's suggestions to include co-exposure to PFOA as a potential confounding factor cannot be supported. The activity should be finished this year. It was agreed to continue this work as a task group, with reporting back into the Working Group by D. Farrar.

### *TFE OECD HPV programme*

Still on track with the SIAR delivery latest June 2010, for discussion at SIAM 31 (Oct 2010). AGC is the lead company. An IUCLID4 file and an ECETOC JACC-report are available to start the SIAR work. Review by the ETS Working Group may be considered 1Q 2010.

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A reprotox data gap on HFP was noted in the OECD HPV SIAR, but it was also suggested in the SIAR this could be filled with read across from information available on TFE. However, in the REACH programme it is now known that TFE does not have reprotox data. Additionally, although a monomer there will be no requirement to fill this data gap in REACH as TFE is a cat 2 carcinogen. In the REACH programme a decision by the registration consortium on how to approach the HFP information requirement on reprotox (e.g. perform a screening study for Annex VIII) is due shortly. ACG leads the TFE registration consortium and DuPont leads the HFP registration consortium.

**Action** Members of the group to report on Monomers progress at each meeting – suggestion that lead company representatives reports.

**Action** Mike to request that REACH Consortia consider reporting to the ETS Working Group to flag potential upcoming science work.

## Surfactants

### APFO related programme

Outstanding manuscripts should be finalised in 2009, and considered for submission to Toxicological Sciences.

- Liver hypertrophy manuscript – Lead author: G Kennedy. Outline available to be discussed at SOT with Cliff Elcombe. Tentative submission date June 2009
- Pancreas manuscript – Lead author: C Elcombe. Contract proposal to deliver final manuscript in 6-months accepted by Management Committee. Tentative submission date Aug 2009, assuming contract was signed.

In the past the Ad-hoc Tox Working Group suggested to classify and label for reproductive and developmental toxicity as Category 3. This involved expert judgement in a field with significant growth in literature activity. It was agreed we would continue monitoring this activity, and consider the impact of new publications.

**Action** Gerry Kennedy/David Farrar/Cliff Elcombe to discuss outline at SOT meeting in March

**Action** M Neal/D Farrar to check the CXR contract status, and remedy the situation if not yet signed.

**Action** G Kennedy to send M Neal the G Olsen paper reviewing human information on reproductive and developmental toxicity for circulation (Done)

### Blood monitoring work programme

Worker monitoring is likely to continue. Interim result reporting by the company is appreciated whenever new information is available. Due to the long half-life it is anticipated that changes in concentrations may be noticeable only after prolonged time. Hence, we will place a “multi-centre” data review on the agenda once a year.

### ‘B’ related work programme

Outstanding manuscript on biomagnification in the food chain (Lead author: I Colombo) should be progressed. W de Wolf to support review.

Outstanding discussion with the Norman-network on the storage and maintenance of the phys-chem database (developed as part of PERFORCE2) should be finalised. Will they agree to this database as a significant ‘in kind’ contribution?

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regulatory criteria and data used for the B-assessment are BCF-values for fish. It is discussed in the academic and regulatory world that bioaccumulation (bioconcentration) in the aquatic environment is different from bioaccumulation in the terrestrial environment. Also, biomagnification in (remote environment) food chains is of continued interest to the regulatory and academic world as part of the efforts to improve identification of potential sources.

We should continue the PFOA efforts if only to demonstrate that PFOA behaves differently from PFOS – this is a responsible care approach. Furthermore, this discussion will impact also other substances of common interest to the Management Committee. However there is little support to finance specific research efforts on PFOA.

This item also links into terminologies used in the foods area (e.g. uptake), the EFSA TDI and potentially into the new EU 7<sup>th</sup> Framework Programme Perfood. We should start/continue to monitor these activities recognising that it may become a higher priority to actively contribute.

**Action All:** If any new papers on PFOA surface please send to M Neal for circulation and archiving.

**Action W de Wolf:** To review draft manuscript I Colombo

## Monitoring scientific literature

We need a literature survey and assessment for its impact on the our industries interest carried out on a regular basis. Apparently there is no skill base for this with the staff of PlasticsEurope. This seems a larger issue for the Management Committee to consider bringing to the attention of PlasticsEurope.

Many people are jumping on the PFC band wagon so we need a very structured approach to obtain a good outcome of the literature monitoring. Could we use the Silicon industry model?– Our current understanding of this model is that the secretariat performs the literature survey, and the initial filtering (e.g. removing papers not related to the remit of the Working Group). The Chairman then usually further filters and pre-selects the reviewers from the Working Group, with the secretary managing the communication and literature flow. Each meeting a 20 min slot is reserved for assessing the literature issues identified. This might be an efficient and cost effective method for the group rather than try this at company level. M DePoortere might be able to help us better understand how they work, and how much resources are required for this.

**Action M Neal:** Check how the silicon industry does this and then take this to the management committee for discussion/support.

## New Surfactants

Partly covered in the notes above.

Ensure we have a watching brief on the impact of new surfactants on manufacture and downstream use. We will continue to use best practice on new chemicals.

Occurrence in drinking water is likely to be a topic related to the new surfactants. How should we handle this before it comes up in the media, or creates regulatory pressures? Other topics may also emerge well before they appear in published literature. Two possible approached for this were discussed.

- Invite a guest speaker to each meeting for a presentation and discussion on a specific subject, such as water contamination.
- Keep track of scientific meetings and ensure attendance by (some) WG members. Members attending will feedback on major items presented and discussed during the next WG meeting.

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aim for an ISO type standard? In the past, Bob Buck, Scott Mabury and John Butennot started a nomenclature paper. Can we obtain a copy of the notes and further progress this?

**Action** W de Wolf to share a glossary chart used during PERFORCE1 with the group.

**Action** J Butenhoff to resurface and share the draft nomenclature paper.

## Data generation formats for registration purpose

Several initiatives in the context of OECD already have work towards standardising formats across regions, and thus this was not considered a priority work item. Furthermore, sharing (regulatory) experiences on specific submissions may be hampered by confidential business information, and thus this was considered a low priority item too.

## Quick updates

**PFC-session ICCE2009, 14 June 2009** (notes on extranet)

Consider to schedule our next meeting on 15<sup>th</sup> June to align with the Sunday workshop on PFC's. If attendance would be severely restricted for the present WG members, then a later date for a Brussels meeting in June will be proposed.

**Action** All to check possibility for attendance, and inform M Neal ASAP. Also indicate available alternative dates in June

**Norman network membership** (notes on extranet)

It is in the benefit of PlasticsEurope to become a member, as this network brings together researchers working in environmental monitoring (analytical chemists), and thus fits into our watching brief on new developments. M Neal could be the administrative contact and J Franklin cover the science monitoring.

**Action** M Neal to see if we can lower the fee and provide our database as sweat equity

**Action** W de Wolf to approach the Management Committee for funds to join

**Action** M Neal to check with G Malinverno then write to P de Voogt that we will not pursue Perforce 3 due to financial constraints.

**Sapphire study Drinking Water Limits** (notes on extranet)

## Schedule meetings 2009 - 2010

Tentative: Stockholm Monday 15<sup>th</sup> June (possibility of attendance to be confirmed by members – to Mike ASAP)

Brussels Tuesday 20 October 2009

Brussels Tuesday 2 March 2010

## AOB & Closing

The membership of the working group requires some further rationalisation given its new remit. The Management Committee should be asked to nominate Company experts.

**Action** M Neal/W de Wolf to discuss with the Management Committee

No additional “any other business” items were brought up. The meeting was closed at 4:10 pm.

## Appendix 1

Please find below the contribution from W L Gore regarding the “where should we be in 5 years” question. I appreciate that WL Gore are coming at this from a different position than the other members simply because of our position in the supply chain, but we feel that the following points are valid for both manufacturers and processors.

In five years, we would like the industry to be at a place where:

- consumers understand that fluoropolymers (e.g. PTFE) are not inherently harmful for the environment;
- consumers recognize that fluoropolymers are safe, valuable and unique materials that:
  - o produce high performance products which benefit society; and are worth their environmental cost;
- the APFO issue has been resolved favourably on a global basis (e.g China); and
- alternative surfactants are being managed in ways to avoid re-creating the APFO issue with the alternative surfactants.

## Appendix 2

AGC see the ETS WG as being, primarily, a reactive group, providing advice on chemicals of interest to the Fluoropolymers Management Committee, as stated in the remit. To that end, we can identify the following issues that should be dealt with over the next 5 years.

1. TFE epidemiology study. This study should be finalised during 2009, using the existing scientific support mechanism.
2. REACH. The ETS should provide scientific support to the REACH consortia of interest to member companies of the PE Fluoropolymers Committee, on a reactive basis.
3. OECD HPV programme. The ETS should use the REACH IUCLID V dossier on TFE to respond to its voluntary obligations on TFE in the OECD HPV programme.
4. The ETS should keep a watching brief on scientific and regulatory developments on PFOA (eg drinking water standards, PERFOOD), with a view to the identification of issues that may impact on the use of the new surfactants
5. The ETS should collaborate on toxicological and environmental issues relevant to the common chemistry of new surfactants, wherever this is possible.

## Appendix 3

Solvay Solexis proposals

Products of concern for the group: APFO and its homologues, fluorinated monomers (TFE,HFP,VDF ), and possibly new fluorinated surfactants.

The regulatory framework of APFO in 5 years from will be most probably quite different and a phased out could not be excluded. Nevertheless, some actions are needed in order to

Proposed activities in a 5-year timeframe:

The activities of the group should be focused on the preparation/conclusion of the papers and publications on the tox aspects still open , in order to create a well referenced work to be used as example or base set info for new future substances. Open items are mainly related to: CXR data (pancreatic cancer and testes cancer) and a deeper understanding of the developmental/ repro matters mainly in relation to relevance to humans (for example statistical analyses on the data which appeared in the recent literature).

Another important issue to be settled is the still open question of the B in the environment, mainly in remote environments such as arctic regions and wildlife and to follow up and or conclude all the remaining task of the existing Environmental Group (FAS) , if any . Of particular interest will be the publication of a comprehensive paper on biomagnification (see draft from Ilaria), and the management of the existing database on physicochemical data on perfluorinated acids.

Preparation of a DB, reviewing all the literature, on APFO related products ( including PFOS and PFOA homologues) in order to get as much info as possible for the future development of new fluorinated products or for sustaining future regulatory requirements.

For the future in general (>5 years), even when APFO will not be any more produced or used, the responsible care for the environmental contamination and for the biopersistency in blood are points to be followed. Longer term activities should include:

Continuous monitoring of the activities and position of third parties, including local Authorities and NGOs, on:

Fluoropolymer decomposition to carboxylic acids

Activities of EU-funded Universities (PERFOOD Project) working on the release of perfluorocompounds along the human food chain, including release from sludges and fertilizers.

Follow-up of the epidemiological and blood level monitoring of general population and workers.

To follow these items the proposal maybe to divide the group in expert subgroups (or task forces working virtually) , to review all the literature published on each specific item and to give feedback during the face to face meetings on the progress of each sub group on the specific matter.

For the monomers, the major tasks should be:

TFE: Conclude and publish the existing multisite Epidemiology Study and continue to follow up the study results.

TFE/HFP /VDF : follow and providing the necessary scientific expertise on possible tox studies to be performed under REACH requirements for registration dossiers (i.e. HFP reprotox and carcinogenicity; TFE reprotox - read across)

New fluorinated surfactants: develop shared formats for generating the data to be submitted to the Regulatory Agencies in EU, USA and Far East, as per the PE Fluoropolymer Management Committee request.





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Avenue E. Van Nieuwenhuyse 4/3 - B -1160 Brussels - Belgium

Tel (32-2) 675 32 97 - Fax (32-2) 675 39 35

VAT BE 416 155 338 – www.plasticseurope.org

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