Discussion on PFHxA

Meeting with DG Environment and DG Grow

3 July 2018

FluoroCouncil
Global Industry Council
for FluoroTechnology

Background and Purpose

- Planned regulatory activities under REACH related to short-chain PFASs
  - RMOA on PFHxA recommending SVHC and restriction proposal
  - RMOA on PFBS recommends similar approach
  - CLH (STOT) for PFBA
  - UBA has initiated preparatory work on a restriction proposal for C4-C7 substances

- Concerns related to short-chain PFASs subject to consultation within the MSC and PBT Expert group

- The FluoroCouncil would like to share its knowledge on PFHxA and views on possible ways forward

Introduction to FluoroCouncil and FluoroTechnology

About the FluoroCouncil

- Represents the world's leading manufacturers of FluoroTechnology based on per-and polyfluoroalkyl substances (PFASs)
- FluoroCouncil has a fundamental commitment to product stewardship and rigorous, science-based regulation, and, as part of its mission, addresses science and public policy issues related to PFASs
- Member companies:
  - Archroma Management LLC
  - Arkema France
  - Asahi Glass Co., Ltd.
  - Daikin Industries, Ltd.
  - Solvay Specialty Polymers
  - The Chemours Company LLC
  - Tyco Fire Products LP (associate member)
  - Dynax (associate member)

FluoroTechnology

Fluorotelomers - Fluoropolymers

Fluorotelomers:

Fluorinated polymers and surfactants

- "Short" fluorinated side-chains that may be attached to organic polymer backbones (polymers)
- **Modify material properties**: surface modification & protection, water & oil repellency; soil resistance; wetting, leveling & spreading
- **Applications**: Textiles, Carpets, Paper, Stone & Tile, AFFF, Paints & Coatings

Fluoropolymers: (Fluoroplastics & fluoroelastomers)

- High molecular weight polymers
- PTFE, Melt Copolymers, Thermoset Elastomers
- Fluorinated "backbone"
- **Material properties**: chemical resistance, thermal stability, resilience (elastomers)
- **Applications**: Breathable membranes, Aerospace Materials, Hydraulic tubing, Chemical Processing , Semiconductor Manufacture, Transportation

Key facts on PFHxA

Toxicological Data for PFHxA Demonstrates Low Human Health Risk

- PFHxA does not exhibit carcinogenicity, mutagenicity, or genotoxicity.
- PFHxA is neither a reproductive nor developmental toxicant and is not an endocrine disruptor.
- The PFHxA toxicity value (0,32mg/kg/d) derived by ANSES is four orders of magnitude higher (less stringent) than the perfluorooctanoic acid (PFOA) toxicity value currently used by the USEPA
  - → The margin of safety for potential daily intake of PFHxA from all routes of exposure in infants is more than 300,000.
  - → Application of standard US EPA drinking water health advisory calculation : 2.2×10^6 ppt compared to 70 ppt for PFOA ,i.e. 32,000 times higher

PFHxA Does Not Bioaccumulate and is Rapidly Eliminated from the Human Body

- PFHxA does not have as high of a binding affinity for proteins as long-chain PFAAs, as demonstrated by numerous protein binding assays
- Rapidly eliminated from all mammalian bodies
  - → Nearly 100% eliminated within the first day after dosing in rodents (Gannon et al 2011)
  - → Elimination half-lives of PFHxA between 0.5 to 1.7 hours in rats and 2.4 to 5.3 hours in monkeys (reviewed in Han 2011)
  - → Elimination kinetics for PFHxA analyzed in humans (a cohort of professional ski wax technicians) : apparent half-life estimated at approximately 28-32 days (Russell 2013)*
- Occurrence studies involving PFHxA have confirmed that PFHxA typically has a low frequency of detection or low level of detection. For these reasons:
  - PFHxA was not included in the USEPA Unregulated Contaminant Monitoring Rule evaluation of the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey (NHANES)

*Not designed as a definitive half-life study

Environmental occurrence is and will most likely remain low

- C6-based fluorotelomer products have been available on the market since the 1970's
  - The notion that this chemistry is new is misleading and false
- PFHxA is present due to one of three pathways: as a manufacturing impurity, as a degradation product or from direct use
- Recent degradation tests on a C6 methacrylate-based fluorinated polymers show very slow degradation: $t_{1/2}$ ca. 3,000 years*
- Effective and responsible use of C6-based fluorotelomer products by employing industry best practice guidance coupled with emission controls – will help ensure that levels of PFHxA remain low
- To date there are no known definitive published temporal studies that support the premise that "exposure to PFHxA is increasing everywhere".

*Publication of this work in preparation

Multiple Full-Scale Treatment Technologies Available to Remove PFHxA and Other Short Chain Acids From Water

- Demonstrated full-scale water treatment technologies are available for the removal of PFHxA to published safe drinking water levels
  - Best Removal/Treatment Options Consists of a “Treatment Train”
    - 2 or more technologies in series
  - Options Include Ion Exchange Resins, Membrane Filtration such as RO, GAC as well as other options
- Treatment technologies capable of complete removal and destruction of PFHxA and other related fluorotechnology products are available as well as in development and will likely evolve to commercial full-scale applications
  - Advanced chemical oxidation techniques
  - Incineration
  - Filtration, Coagulation, RO membranes etc.

Industry and Market Reliance on C6 Fluorotelomer-based Chemistry

- The main applications include performance textiles, carpeting, paints and coatings, high hazard Class B fire fighting foams (AFFF), electronics, food packaging, as well as building and construction.

The **MIDWOR-LIFE analysis**, co-funded by European Union, assessed as regards textiles:
Fluorine free alternatives only offer a similar level of protection with the singular property of water repellency.

- Non-fluorinated alternatives may be used in applications requiring limited performance: water-repellency and water-based stains only, fire fighter training and extinguishing of some Class B fires
- Substitution from C8- to C6-based products was the result of years of research, product redesign and reformulation as well as significant customer requalifications, work with governmental agencies, and significant investments.

C6 fluorotelomer-based substances are key in supporting and completing the transition from C8 fluorotelomers globally

Continued efforts in the field of Best Practices

- The FluoroCouncil works with downstream sectors to develop Best Management Practices along the life cycle of products
  - BAT/BEP Textile : For Textile Mills and Finishers, as well as for Packagers, Brands and Retailers
    - Safety Data Sheet (SDS) and Technical Data Sheet (TDS) advice
    - Material reuse/recycle and waste disposal
    - Emissions' minimisation
  - BEP Fire fighting foams :
    - Covers use conditions, training, containment and disposal
    - The FluoroCouncil and industry recommends to avoid the use of AFFF for training purposes
    - Transition to short-chain fluoro-chemicals and responsible use of these will greatly and immediately diminish the emissions of long-chain PFAS

PFHxA Assessment of Risk Considerations

- PFHxA exhibits low overall toxicity
- Soil biodegradation studies on C6 fluorotelomer side-chain polymers provide a degradation half life of thousands of years
- Large Margins of Safety using the published derived Reference Dose
  - Several Orders of Magnitude Margins in both human exposure and via drinking water
- Current use patterns, trends, emission controls and best practices will help keep both presence and exposure low

The data do not support the listing of PFHxA as SVHC

Options going forward

- We do not believe the data on PFHxA provide basis for **SVHC** identification based on an equivalent level of concern to PBT/vPvB
- Data are available to quantify the risk, which questions the use of the precautionary principle
- REACH Restriction process requires in-depth risk and socio-economic assessment
- Continuous efforts to minimise emissions to the lowest levels technically feasible via application of BAT/BEPs through the entire value chain
- US EPA PFOA Stewardship Programme, a successful example of authorities-industry cooperation

Thank you

Human monitoring data

Country / Study	Sample Size	LOD (ng/mL)	FOD (%)	Citation
U.S. / C8 Health Study	67,000	<0.5	**53%**	Frisbee (2009)
New Zealand / POP Study	747	<0.5	**0%**	New Zealand Ministry of Health (2013)
U.S. / American Red Cross	2,294	<0.02 – 0.1	**6%**	Olsen (2017)
South Korea	1,874	<0.11	**0%**	Lee (2017)
Canada / Health Measures Study	1,524	<0.1	**2%**	Health Canada (2013)
Japan / Exposure to Chemical Compounds	326	<0.1	**0%**	Japan Ministry of the Environment (2016)
China / General Population Study of Three Provinces	202	<0.01	**53%**	Li (2017)
Norway / A-Team Study	61	<0.045	**0%**	Poothong (2017)

* Second analysis of 1,180 samples by another laboratory: PFHxA detected in none of the samples

Degradation Test Data

Test name	Method	Test Item	Report number	Status or deadline	Conclusion
Inherent Biodegradability Zahn-Wellens-Test / EMPA Test	OECD302B (adapted)	Perfluoro polymer dispersion	AZW15653	Finalized	The results clearly show that up to day 55 only the 6-2 FtOH that remained in the test solution long enough, was transformed to PFHxA. No degradation of the polymer was determined.
Aerobic Transformation in Soil	OECD307 (extended)	Perfluoro polymer dispersion	ASB15653	Finalized	The test item has to be considered to be very slowly transformed by aerobic biological processes in soil (t1/2 > 2900 years in all four soils tested)
Anaerobic Transformation in Soil	OECD307 (extended)	Perfluoro polymer dispersion		Ongoing Sept-2018	Interim results show longer half-life time than in aerobic conditions

- These recent degradation tests on a C6 methacrylate-based fluorinated polymers show very slow degradation: $t_{1/2}$ ca. 3,000 years
  - Test conclusion: sum of all potential degradation products less than 0.04% of 6-2 FTOH equivalents in all four soils
  - Transformation rates would be even slower in soils with less aerobic biological activity. Studies under anaerobic conditions are underway.
  - The test protocols were conducted along OECD testing method guidelines and were approved the US EPA.