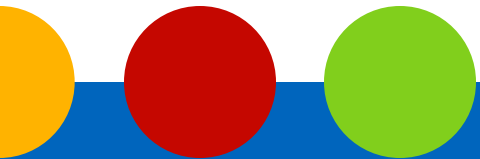


# Enforceability of Restrictions in the absence of analytical methods



ECHA Enforcement Forum

Helsinki

Nov 5-7, 2019

**PlasticsEurope**  
Association of Plastics Manufacturers  
*Fluoropolymers Product Group*

# Enforceability of Restrictions in the absence of analytical methods

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- REACH restrictions trigger a lot of business-to-business questions and compliance action even before a regulation is implemented.
- Plastics Europe supports scientifically based restriction limits based on established REACH criteria.
- Practical, validated, standardized and commercially available analytical methods are critically important to:
  - Enable sound business decision-making and verify compliance to regulations
  - Avoid market confusion
  - Allow for efficient implementation
  - Require supply chain adherence; and
  - Enforce restrictions

1. Validated and Standardized (high quality control standard (Limit of detection, Recovery, Reproducibility, Measurement uncertainty))
2. Robust (applicability to sample matrices and target substances, test effort proportional to the benefit)
3. Commercially Available (multi-laboratory; not only one laboratory who can perform test)

Method validation is specific to substrate, detection range.  
Quality control needs to inherent to any method.

# Interlaboratory Reproducibility for PFAS is a major issue

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## Perforce Study 2004/05: 21 laboratories

Poor Variance for PFOS in Water 95%, PFOS in Fish 125%

Reference; Leeuwen. S.P.J. van, Karrman, A., Bavel, B. van, Boer, J. de & Lindstrom, G. (2006). Environmental Science & Technology, 40, 7854.

## EPA Method 8327: SW-846 Multi-Lab Validation Study June 2019:

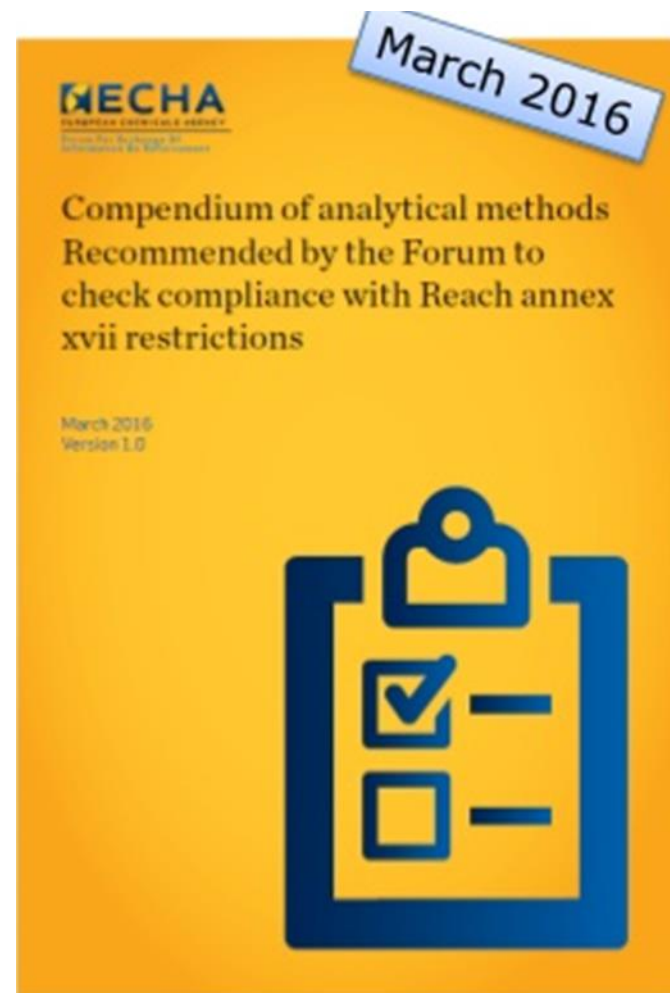
Water and waste water

- 12 laboratories were provided with supplies of consumables to reduce variability
- 1/3 of laboratories not included in evaluation due to poor reproducibility
- 11 analytes out of 24 are indicated as poor performers with respect to reproducibility, response, recovery, stability and/or chromatography.

# Methods provided by PlasticsEurope for addition to compendium of analytical methods

3M Method for PFAS in Article of Commerce
AFFF_Guidance
Daikin Advanced Analysis method for C6/C8
Chemours FP Extraction Method & ISO 25101
Chemours FT Extraction and Analytical Method

Different Matrices require different method.



# Different matrices require different methods

	PFOA	PFOA-related substances	Matrix
<b>Fluoropolymers</b>			
3M Method for PFAS in Article of Commerce	X		Dispersion, powder, pellet, articles
Chemours FP Extraction Method & ISO 25101	X		Polymer cube and fine powders
<b>Fluorotelomers</b>			
AFFF Guidance	X	X	Aqueous Film Forming Foam (AFFF) and Alcohol resistant AFFF concentrates
Daikin Advanced Analysis method for C6/C8		X	Treated Fabrics
Chemours FT Extraction and Analytical Method	X	X	Fluorotelomer-based intermediates and products

- EU Commission sponsored development of practical, validated standardized and commercially available analytical methods. This could be achieved by the creation of a dedicated CEN group (European Standardization Organizations).
- We would like to ask Enforcement Forum to include our proposed methods to ECHA's compendium as recommended or standardized methods.
- Enforcement Forum should publish their position on current status of method development for Annex 68 to provide guidance for business-to-business interactions.
- We would like to encourage the Enforcement Forum to make their comments on REACH Restriction dossiers public by participating to the official public consultation process.



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