



Analytical Characterisation of Polymers for EU Regulatory Purposes

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Regulatory background

Article 138 (2) of the REACH Regulation sets out criteria to potentially '*present legislative proposals for selecting polymers for registration...*'

Article 6(3) of the REACH Regulation sets out criteria on the obligation of polymer manufacturers/importers.

REACH Regulation relies on the OECD polymer definition.

- The proposal for possible polymer registration includes:
- information on the polymer structure and composition
 - analysing low molecular weight polymerised constituents
 - detailed analytical characterisation of the polymers.

The REACH revision is currently on hold.

Why oligomers selected?



Currently no registration obligation for polymers under REACH

Substances of polymeric nature that do not meet the polymer definition under REACH, fall within the scope of the registration.

Oligomers can be considered as the low MW analogues of typical polymers.

Sufficiently large pool of substances for a statistical assessment within the REACH database (ca. 400 substances, 1400 registrations).

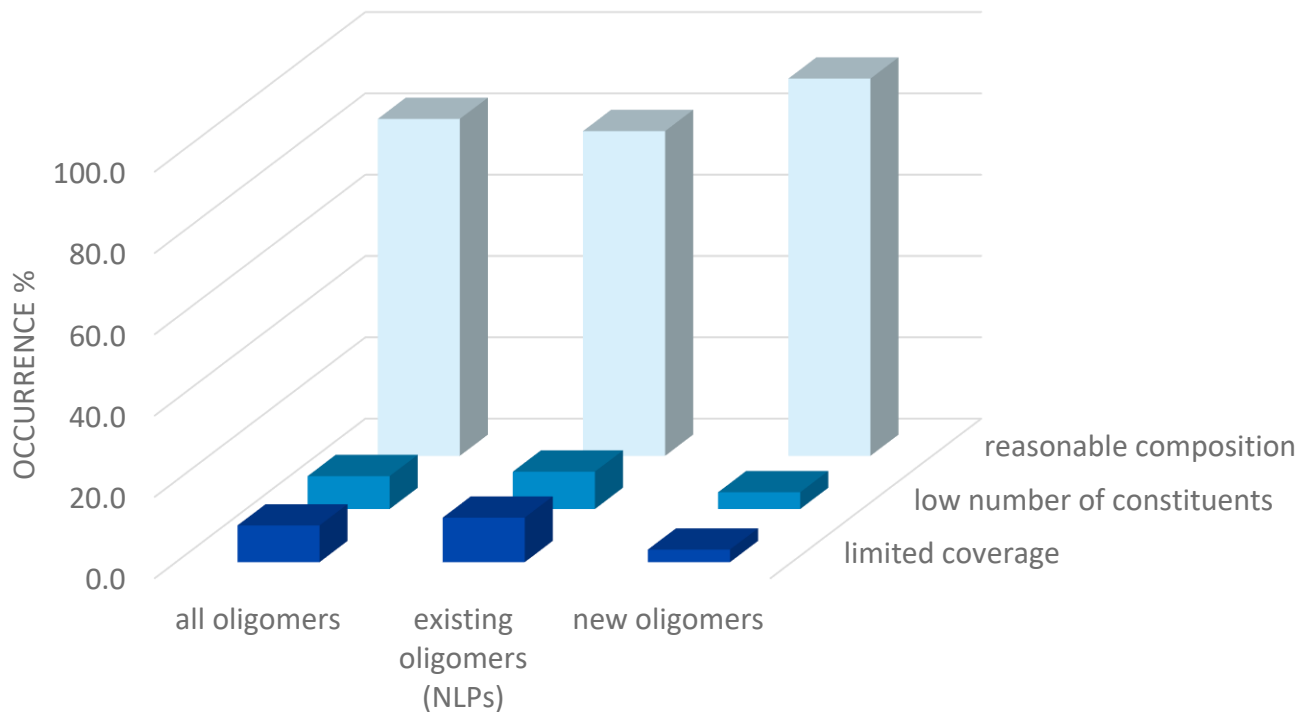
Aim of the assessment



- Gathering statistical data on the REACH registered oligomers based on commonly used separation techniques (GC, HPLC, GPC, MALDI-TOF) to:
- Assess the relation between the reported compositions and the type of analytical techniques submitted in the dossiers.
 - Gain further insight on how the low molecular weight polymerised constituents (below 1000Da) have been characterised.

GC: Gas chromatography; HPLC: High-performance liquid chromatography;
GPC: Gel permeation chromatography; MALDI-TOF: Matrix-assisted laser desorption ionization-time of flight

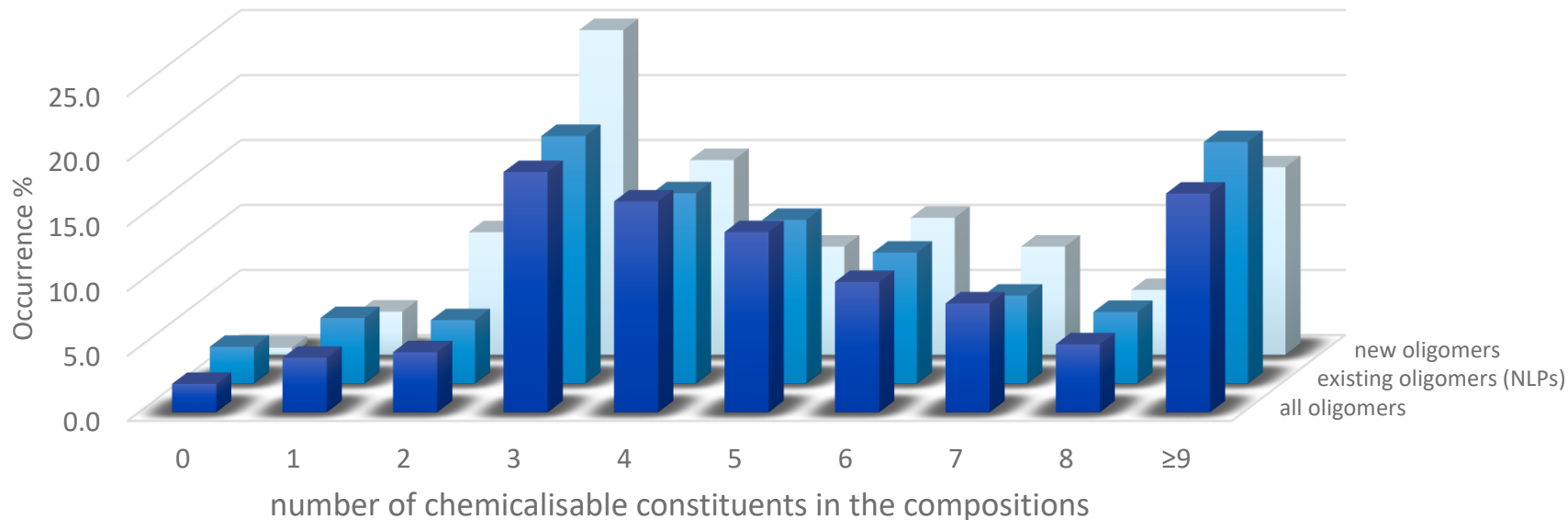
Quality of the compositions reported for different oligomers



ECHA has developed a scoring system to indicate the quality of the identification of the substances.



Quality of the reported constituents in the compositions

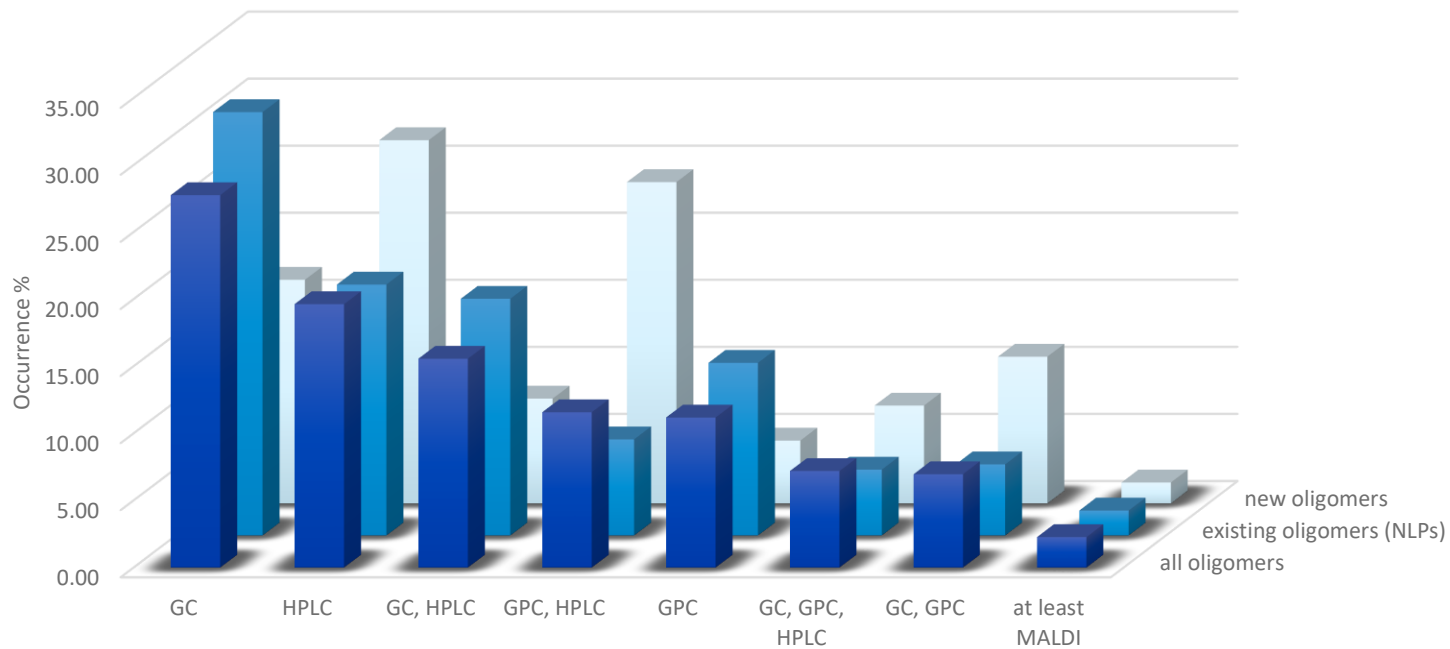


Chemicalisation checks whether a structure can be derived from the information of the reported constituents.

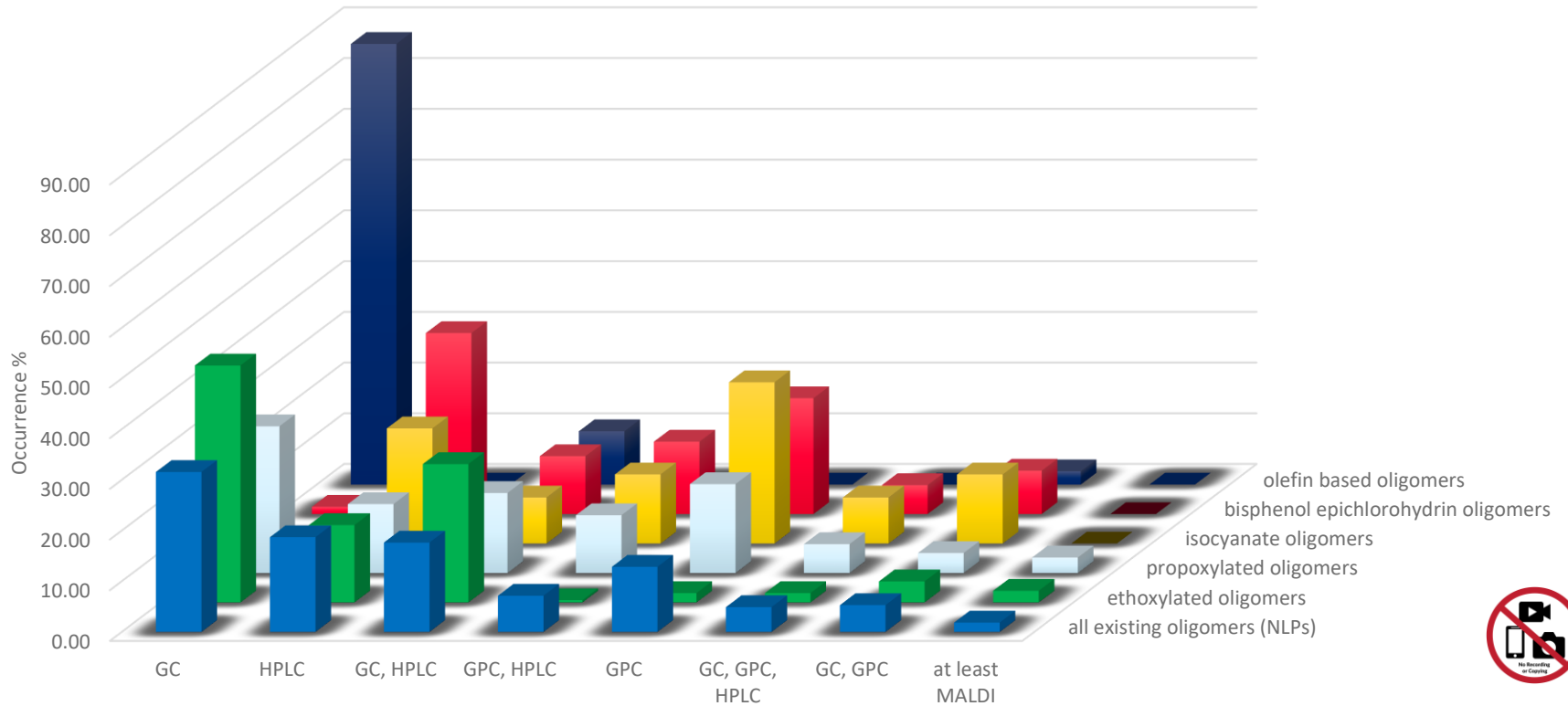
No step change in the results between existing and new oligomers.



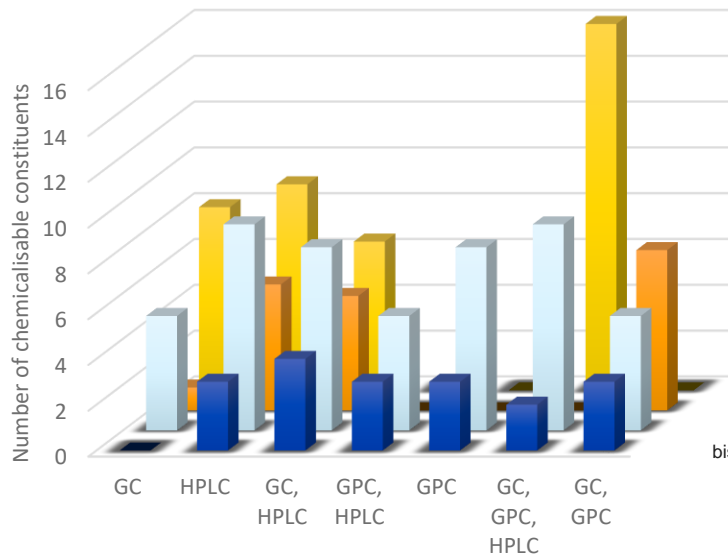
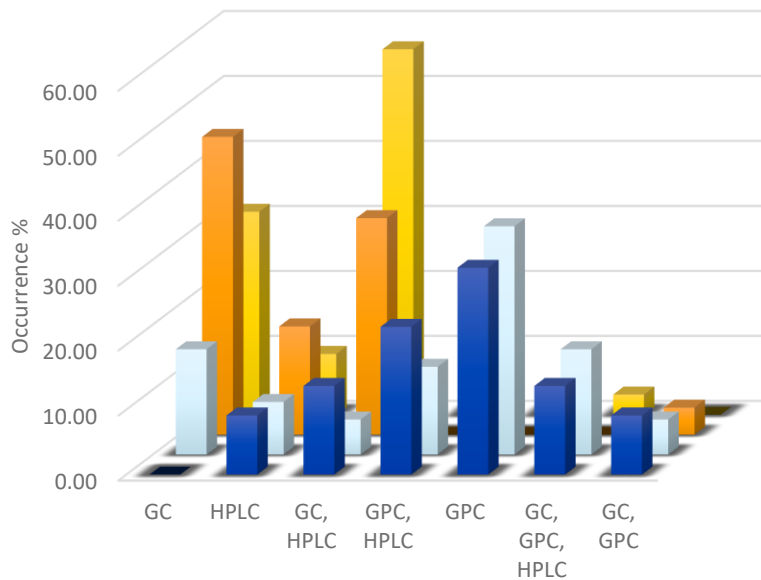
Analytical methods used for the different oligomers



Analytical methods used for some of the existing oligomers (NLPs)



Trends in analysis of the same substances (over 20 Registrants for every substance)



ethoxylated alcohol
esters of propoxylated polyol
propoxylated polyol
bisphenol epichlorohydrin derivative

Main methods selected might not always be the most suitable ones.
Case-by-case assessment needed for the different substances.



Oligomers in environmental hazard assessment

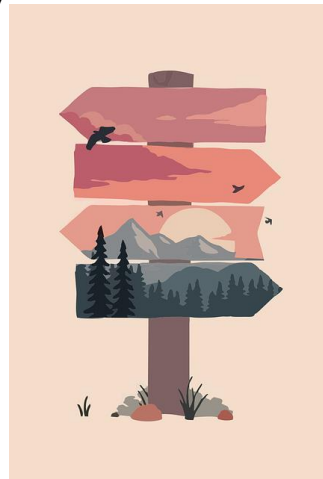
- Correct identification of polymers is prerequisite for their hazard assessment and proportionate testing under the future regulatory scheme.
- Presence of low molecular weight polymerised constituents in the polymer released to environment may affect its bioavailability, environmental fate and toxicity.
- Ecotoxicological concern raises with the increase of <1000 Da oligomeric species content (increased uptake by organisms, higher bioavailability).
- The extent of migration from polymer matrix and (eco)toxicological properties of oligomers are often unknown.

Main conclusions

- In general, REACH registrants deliver a rather high subdivision of the composition of oligomers.
 - In this study: oligomers used as 'proxy' for low molecular weight polymerised constituents.
- The choice of analytical methods is generally scattered within substance families and registrants of the same substance, too.
- The correlation between the choice of the analytical method and the composition breakdown is limited/shows different trends.

Problems to be solved

- The use of different analytical approaches may complicate and compromise the correct identification of polymers and ultimately the implementation of the Regulation.
- Standardisation of methods used would facilitate the task of the Registrants.
 - How to push for standardization?
 - How to select the best suitable analytical methods?
- How to test polymers in a proportionate way for assessing the ENV hazard?



It should be a joint effort from Industry, Research/Academia, ECHA, European Commission.

Thank you

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