FEICA®

The European voice of the **adhesive and sealant industry**

FEICA WEBINAR

The Upcoming Registration of Polymers under REACH

23 June 2021

16:00 - 17:30 Brussels CET

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Proceedings

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- The presentation slides will be sent to all webinar registrants

Speakers

Ms Paula Diaz
FEICA
Regulatory Affairs Manager

Ms Tracy Williamson
Chief, Industrial Chemistry Branch, New Chemicals Division
Office of Pollution Prevention and Toxics, U.S. EPA

Mr Claus Urban
Global Regulatory Affairs Manager at Sika
FEICA Polymers Requiring Registration (PRR) TTF Chair

Ms Kim Suetens
Scientific and Regulatory Affairs Advisor at Soudal
FEICA Polymers Requiring Registration (PRR) TTF Vice Chair

MARKET

7 market segments

employs more than **45,000** people

14 technologies

470 million euros on Research and Innovation investment

17 billion euros contribution to the EU economy

2% of European chemical industry's turnover

5 million tonnes of adhesives and sealants

250,000 different products for the most diverse applications

COMMUNITY

800 adhesives and sealants producers in Europe

165 adhesives and sealants experts

ACTIVITIES

6 key projects

- Circular economy
- Safe use of mixtures
- Good practice
- Food contact
- Innovation and education
- Model EPDs

85 publications annually

VISION

1 FEICA Vision

"The adhesive and sealant industry is committed to enabling a growing population to live a better life and to use the planet's resources responsibly and efficiently."

FEICA's mission is to support the industry in this objective by focussing on **sustainable development, health & safety and innovation**.

FEICA®

COMMUNICATION

10,000 connections on LinkedIn

5,000 followers on Twitter and Instagram

8 events per year ▶ bringing together **3,000** industry stakeholders

Source market information: FEICA/Smithers Market Report 'European Adhesives and Sealants Market 2019-2024

Agenda

16:00 Introduction and legal background
by Ms Paula Diaz, FEICA Regulatory Affairs Manager

16:15 Polymers regulation in the United States
by Ms Tracy Williamson (EPA), Chief, Industrial Chemistry Branch, New Chemicals Division, Office of Pollution Prevention and Toxics, U.S. EPA

16:30 Use of polymers in adhesives and sealants
by Mr Claus Urban, Global Regulatory Affairs Manager at Sika, FEICA Polymers Requiring Registration (PRR) TTF Chair

16:45 Adhesives and sealants industry perspective on the registration of polymers
by Ms Kim Suetens, Scientific and Regulatory Affairs Advisor at Soudal, FEICA Polymers Requiring Registration (PRR) TTF Vice Chair

17:10 Q&A, moderated by Ms Paula Diaz

17:30 Close of the webinar

Agenda

16:00	**Introduction and legal background** ***by Ms Paula Diaz, FEICA Regulatory Affairs Manager***
16:15	Polymers regulation in the United States *by Ms Tracy Williamson (EPA), Chief, Industrial Chemistry Branch, New Chemicals Division, Office of Pollution Prevention and Toxics, U.S. EPA*
16:30	Use of polymers in adhesives and sealants *by Mr Claus Urban, Global Regulatory Affairs Manager at Sika, FEICA Polymers Requiring Registration (PRR) TTF Chair*
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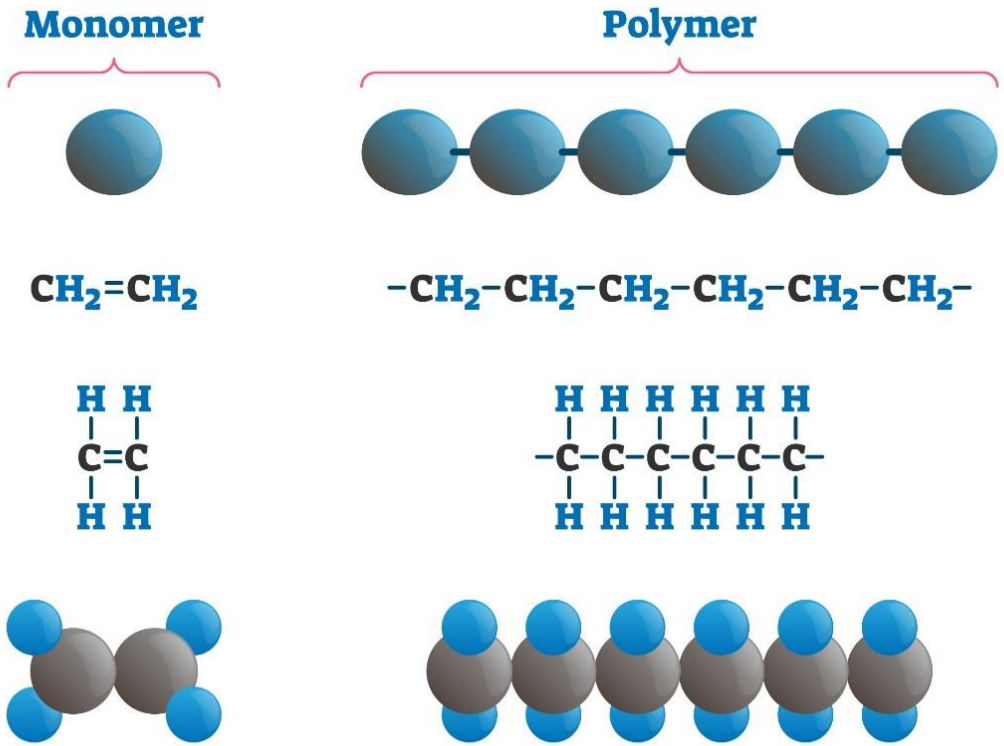
Ms Paula Diaz
FEICA
Regulatory Affairs Manager

Introduction and legal background

Current legal obligations



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- **All substances placed on the European market over 1 ton a year** must be **registered** as per Regulation EC/1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- Polymers are **currently exempted from registration** under REACH, even if their building blocks (monomers) are registered in any case

Registration of polymers - foreseen in REACH

- However, REACH Art 138(2) placed an obligation for a further review of polymers and comparison of the risks compared to other substances.

- **Therefore, the European Commission is working to define criteria to identify polymers that could potentially be subject to registration requirements**

Steps towards the registration of polymers

- The **Wood/PFA report** was published in July 2020 to:
  - Identify polymers requiring registration (PRR)
  - Propose grouping criteria
  - Define the registration process
  - Assess costs/benefits of polymers registration

- A **CARACAL subgroup** was created to engage stakeholders in the discussion, including downstream users

- The European Commission will draft a **proposal to amend REACH** to establish registration requirements for polymers in **2022**

Registration process

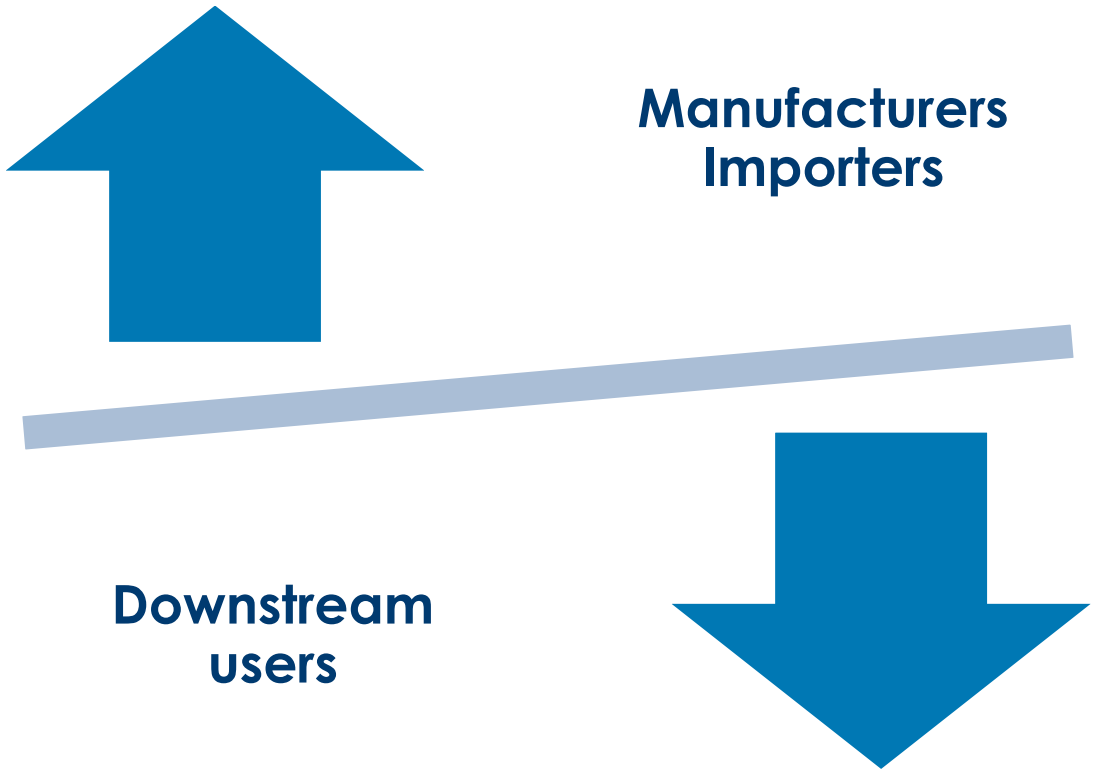
- **Phase 1 – PRR identification criteria**
  - To decide whether a polymer requires registration
  - Exemptions will apply

- **Phase 2 – Group PRRs that can be registered together**
  - Grouping ideas being discussed

- **Phase 3 – Fulfil the information requirements**
  - Adaptation for polymers

- **After registration – Evaluation, authorization and restriction**

Current roles under REACH

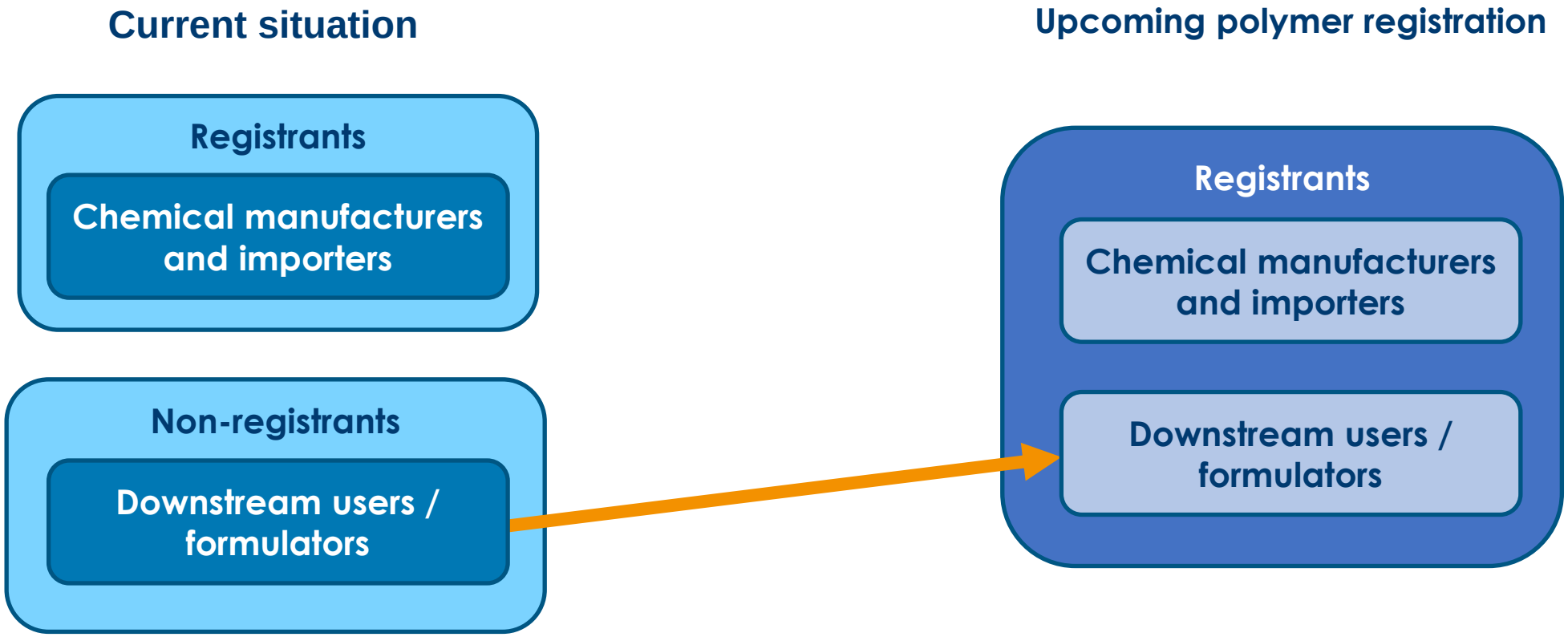


- Manufacturers and importers are multinational companies producing or importing chemicals as their core business

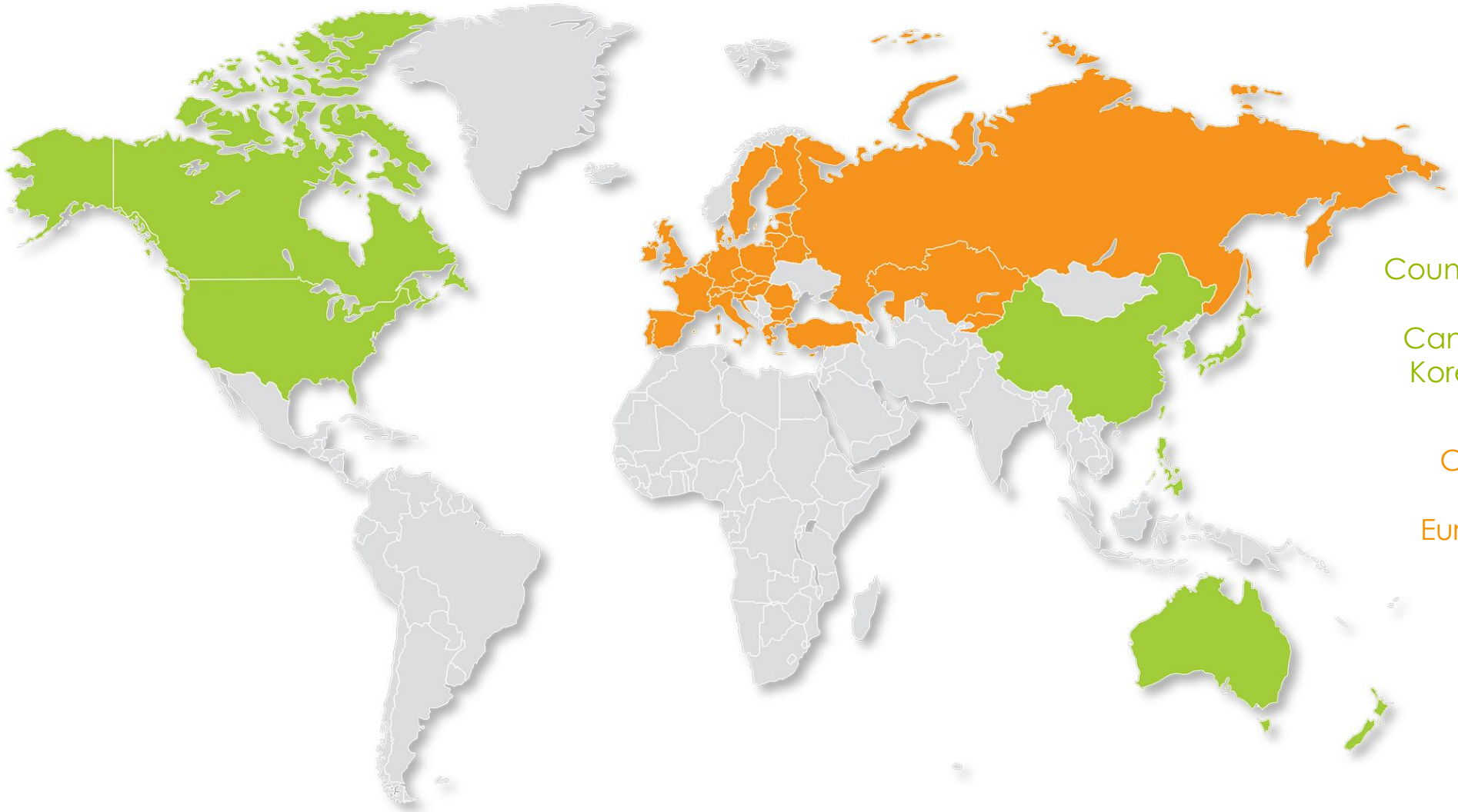
- Downstream users use chemicals as raw materials to produce their products

  Their main business is the manufacture of products such as adhesives and sealants, cosmetics, detergents, construction products, etc.

Paradigm change for downstream users



Chemical compliance regulations - POLYMERS



Countries/Regions with polymer registration schemes: USA, Canada, Japan, China, South Korea, Taiwan, Australia, New Zealand, Philippines

Countries where monomers need to be registered: European Union, Switzerland, UK, Turkey, Eurasian EU

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Tracy Williamson
Chief, Industrial Chemistry Branch
New Chemicals Division
Office of Pollution Prevention and Toxics
U.S. EPA

Polymer Exemption for New Chemicals under the U.S. Toxics Substances Control Act (TSCA)

Background

- The Toxic Substances Control Act (TSCA) new chemicals program serves as a "gatekeeper" role to help to manage potential risk human health and environmental from chemicals new to the marketplace.
- TSCA section 5(a) requires that any person planning to manufacture or import a new chemical substance (i.e., a chemical not on the TSCA Inventory) submit notice to EPA prior to commencing that activity. This notice is known as a premanufacture notice (PMN).
- EPA is required to review these PMNs within 90 days, assess the potential risks to human health and the environment of the chemical, and to make an affirmative determination.
- Where potential risks are identified, EPA must take action to mitigate those risks before the chemical can enter commerce.

The Polymer Exemption

- TSCA section 5(h)(4) provides EPA authority to issue exemptions to TSCA section 5(a) reporting requirements.
- The polymer exemption is intended to encourage the manufacture of safer polymers by reducing industry's reporting burden for this category of chemical substances, and to concentrate the Agency's review resources on substances expected to pose higher risk.
- Under the terms of the polymer exemption, manufacture and distribution of polymers meeting the exemption criteria can take place without submission of a PMN or an exemption notice prior to commencement of manufacture for a commercial purpose (40 CFR 723.250). Submitters self-determine eligibility.
- If a submitter self-determines they are ineligible for the exemption, and the substance they wish to manufacture/import is not listed on the TSCA Inventory, they must submit a new chemical notice using the Premanufacture Notice form for EPA review.

Reporting and Recordkeeping

- Manufacturers of exempted polymers are subject to comprehensive recordkeeping requirements to document compliance with the exemption criteria. 40 CFR 723.250(j).
- Manufacturers of exempted polymers are required to submit an annual report on the number of exempted polymers for which their manufacture or importation commenced under terms of the exemption during the preceding calendar year. 40 CFR 723.250(f)

Exemption Amendments

- In 1995 amendments were made to:
  - eliminate unnecessary EPA review of eligible (low risk) polymers,
  - transfer the burden of ensuring eligibility from EPA to the manufacturer, to
  - encourage the manufacture of safer chemicals and substances produced with low exposure and low release, and
  - reduce the number of PMNs through exemption (34 percent of PMNs filed before the amendments would qualify for polymer exemption).

- The polymer exemption now relies on comprehensive recordkeeping for compliance purposes, adopts the international OECD (Organization for Economic Cooperation and Development) definition of "polymer" and amends the "two percent" reporting rule for polymers to allow greater flexibility for polymer manufacture.

➢ Read the 1995 amendments (60 FR 16298; March 29, 1995)

Exemption Amendments, cont'd

- In 2010 amendments were made to:
  - exclude from eligibility polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF3- or longer chain length, out of concern for PFAS.

- This change was necessary because, based on current information, EPA can no longer conclude that these polymers "will not present an unreasonable risk to human health or the environment" under the terms of the polymer exemption rule, which is the determination necessary to support an exemption under TSCA section 5(h)(4).

➢ Read the 2010 amendments (75 FR 4295; January 27, 2010)

Exemption Eligibility

- The eligibility criteria for the polymer exemption are:
  - Polymers with molecular weight (MW) of 1,000 daltons or greater and less than 10,000 daltons are eligible, with restrictions on low MW species and reactive functional groups;
  - Polymers with MW of 10,000 daltons or greater, with restrictions on low MW species.

Exemption Eligibility cont'd

- The 1995 amendments made the polymer exemption generally less restrictive:
  - Allowable elements has been expanded to include chlorine, bromine, iodine as monatomic counterions; and fluorine, chlorine, bromine and iodine if covalently bound to carbon;
  - Biopolymers which meet the polymer definition are no longer excluded;
  - Polymers that are cationic or anticipated to become cationic in aquatic environments were made eligible for exemption if the polymer is solid, not soluble or dispersible in water and will be used only in solid phase, or equivalent weight is equal to or greater than 5,000; and,
  - There is an expanded list of specified reactants for polyesters.

Exclusions

(1) Cationic polymer

- A polymer cannot be manufactured under this section if the polymer is a cationic polymer as defined under paragraph (b) or
- if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment unless:

  (i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase…, or

  (ii) The combined (total) functional group equivalent weight of the cationic groups in the polymer is ≥5,000.

➢ Note: Includes N, P, S cations

Exclusions cont'd

(1) Cationic polymer cont'd

- OK under polymer exemption:
  - A polymer that is anticipated to become cationic and that is:
  - a solid,
  - not soluble or dispersible in water, and
  - will be used only in the solid phase
  - A polymer that is anticipated to become cationic and for which the FGEW (combined/total) of the cationic group(s) is ≥5,000
- Not OK under polymer exemption:
  - A cationic polymer as defined under 40 C.F.R. §723.250(b)*
  - A polymer that is reasonably anticipated to become a cationic polymer in a natural aquatic environment and does not meet either of the two conditions above

* *Cationic polymer means a polymer that contains a net positively charged atom(s) or associated groups of atoms covalently linked to its polymer molecule.*

Exclusions cont'd

(2) Elemental limitation

(A) (i) A polymer manufactured under this section must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

(ii) A polymer cannot be manufactured under this section if it contains as an integral part of its composition, except as impurities, any elements other than the following:

(A) The elements listed in paragraph (d)(2)(i) of this section.

(B) Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counterions

Na^+, Mg^{2+}, Al^{3+}, K^+, Ca^{2+}, Cl^-, Br^-, or I^-.

(C) Fluorine, chlorine, bromine, and iodine covalently bound to carbon.

(D) <0.20 weight % of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.

Exclusions cont'd

(3) Polymers which degrade, decompose, or depolymerize

- A polymer cannot be manufactured under this section if the polymer is designed or is reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so.

- For the purposes of this section, degradation, decomposition, or depolymerization mean those types of chemical change that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light, or microbial action.

➢ **Example**: flame retardant

Exclusions cont'd

(4) Polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory

- A polymer cannot be manufactured under this section if the polymer being manufactured or imported is prepared from monomers and/or other reactants (that are either charged to the reaction vessel or incorporated in the polymer at levels of greater than 2 weight percent) that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

(5) Water absorbing polymers with number average molecular weight (MW) 10,000 and greater

- A polymer cannot be manufactured under this section if the polymer being manufactured or imported is a water absorbing polymer and has a number average MW ≥ 10,000 Daltons.
- For purposes of this section, a water-absorbing polymer is a polymeric substance that is capable of absorbing its weight of water.
  - **Example**: hydrogels, e.g., for disposable diapers

Exclusions cont'd

(6) Polymers which contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length

– Except as provided in paragraph (d)(6)(i), after February 26, 2010, a polymer cannot be manufactured under this section if the polymer contains as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF3- or longer chain length: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012.

E1 Exemption

40 C.F.R. §723.250(e)(1)

- Molecular Weight Parameters:
  - $1000 \leq MW < 10{,}000$
  - Oligomeric content:
    - <10 weight % below 500 Daltons
    - <25 weight % below 1000 Daltons
- Functional Group Content:
  - low-concern FGs: can contain an unlimited amount
  - moderate-concern FGs: FGEW ≥ 1000
  - high-concern FGs: FGEW ≥ 5000

E2 Exemption

40 C.F.R. §723.250(e)(2)

- Molecular Weight Parameters:
  - MW ≥ 10,000
  - Oligomeric content:
    - <2 wt% under 500 Daltons
    - <5 wt% under 1000 Daltons

➢ Note: There is no upper Molecular Weight limit.

E3 Exemption

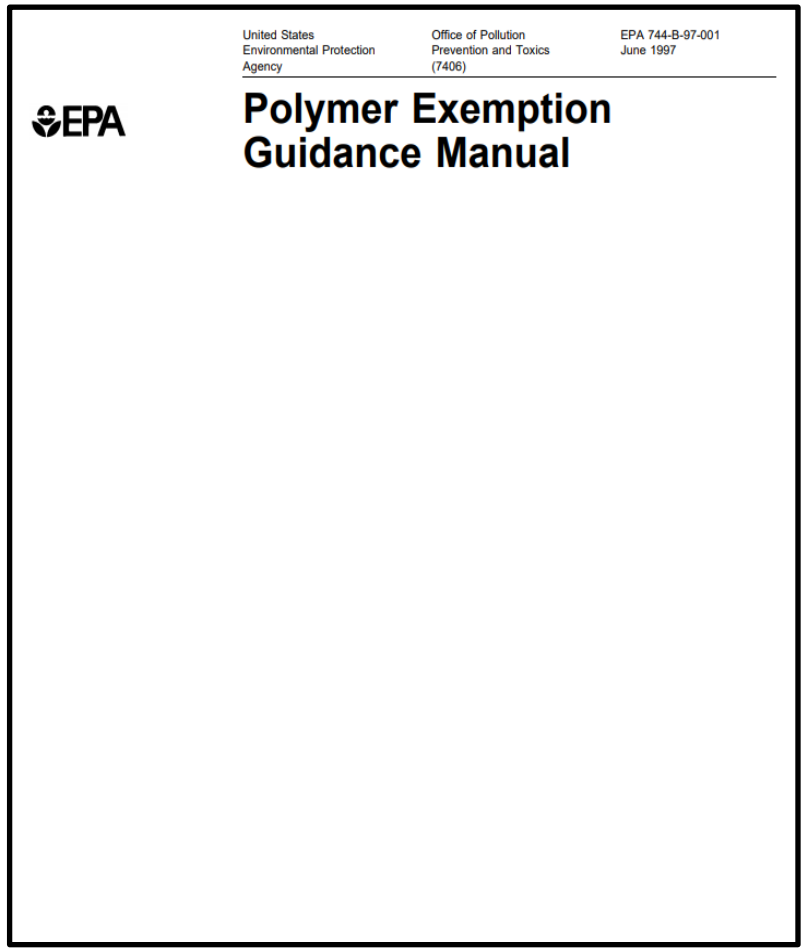
40 C.F.R. §723.250(e)(3)

- Polyesters made of allowable monomers:
  - Polyester means a chemical substance that meets the definition of polymer and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal monomer units together.
- Allowable Monomers/Reactants:
  - Made only from one or more of the reactants in table 1 in §723.250(e)(3)

➢ Note: There are no Molecular Weight parameters.

Guidance

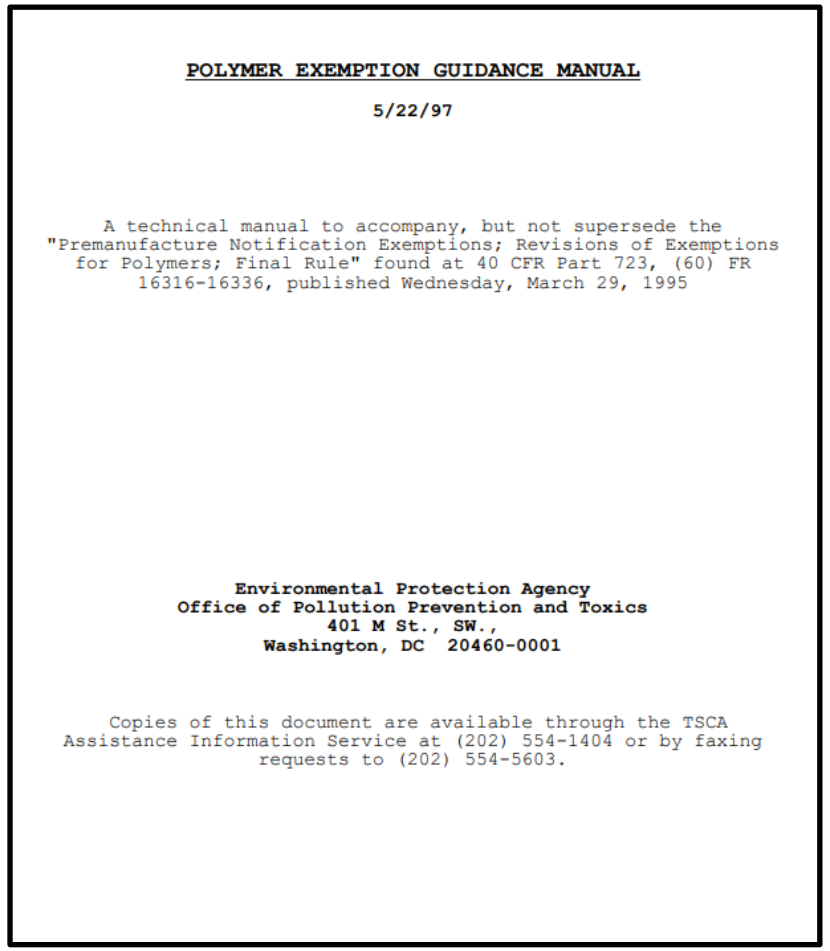
https://www.epa.gov/sites/production/files/2015-03/documents/polyguid.pdf



United States Environmental Protection Agency | Office of Pollution Prevention and Toxics (7406) | EPA 744-B-97-001 June 1997

EPA

Polymer Exemption Guidance Manual



POLYMER EXEMPTION GUIDANCE MANUAL

5/22/97

A technical manual to accompany, but not supersede the "Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Final Rule" found at 40 CFR Part 723, (60) FR 16316-16336, published Wednesday, March 29, 1995

Environmental Protection Agency
Office of Pollution Prevention and Toxics
401 M St., SW.,
Washington, DC 20460-0001

Copies of this document are available through the TSCA Assistance Information Service at (202) 554-1404 or by faxing requests to (202) 554-5603.

Elemental Allowances and Exclusions

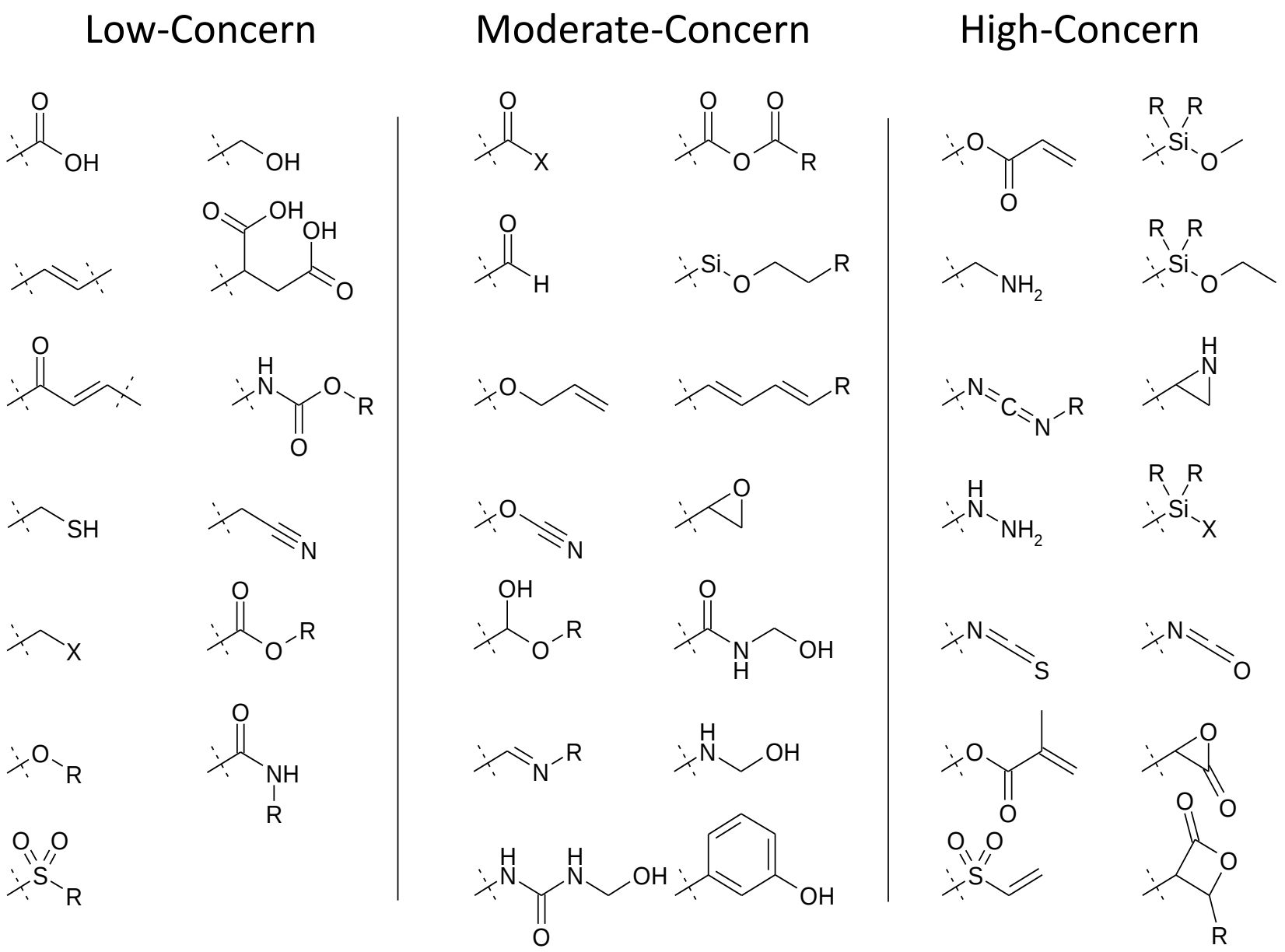
Elemental content

- OK under polymer exemption:
  - C, H, N, O, Si, S (at least two or more)
  - Na^{+}, K^{+}, Ca^{2+}, Mg^{2+}, Al^{3+}, Cl^{-}, Br^{-}, I^{-} (ok as counterions)
  - F, Cl, Br, I (ok if covalently bound to carbon)
  - Li, B, P, Cu, Fe, Mn, Ni, Sn, Ti, Zn, Zr (ok if <0.20 wt % of any combination)
- Not OK under polymer exemption:
  - Rb, Cs, Fr (alkalai metals)
  - Be, Sr, Ba, Ra (alkaline earth metals)
  - He, Ne, Ar, Kr, Xe, Rn (noble gases)
  - Ga, In, Tl, Pb, Bi (post-transition metals)
  - Ge, As, Sb, Te, Po (metalloids)
  - Se (non-metals)
  - At (halogens)
  - Sc, V, Cr, Co, Y, Nb, Mo, Tc, Ru, Rh, Pd, Ag, Cd, Hf, Ta, W, Re, Os, Ir, Pt, Au, Hg, Rf, Db, Sg, Bh, Hs, Mt, Ds, Rg, Cn (transition metals)
  - Lanthanides, Actinides, elements of unknown properties

E1 Exemption
Combined Functional Group Equivalent Weight (FGEW)

Minimum Combined FGEW	None[1]	1,000	5,000	1,000[2]	5,000[2]	5,000	5,000[2]
Low Concern	X			X	X		X
Moderate Concern		X		X		X	X
High Concern			X		X	X	X

[1]There is no FGEW limit for polymers containing only low concern FGs.
[2]When calculating combined FGEWs for substances with moderate- and/or high-concern FGs, low-concern FGs are not included in the calculation.


Low-Concern
Moderate-Concern
High-Concern

E3 Exemption - Allowable Monomers

Monobasic Acids and Natural Oils	
65-85-0	Benzoic acid
120962-03-0	Canola oil
8001-31-8	Coconut oil
8001-30-7	Corn oil
8001-29-4	Cottonseed oil
143-07-7	Dodecanoic acid
128952-11-4	Fats and glyceridic oils, anchovy
91078-92-1	Fats and glyceridic oils, babassu
68153-06-0	Fats and glyceridic oils, herring
8002-50-4	Fats and glyceridic oils, menhaden
93334-41-9	Fats and glyceridic oils, sardine
8016-35-1	Fats and glyceridic oils, oiticica
67701-08-0	Fatty acids,C16-18 and C18-unsatd.
61789-44-4	Fatty acids, castor-oil
61788-47-4	Fatty acids, coco
61789-45-5	Fatty acids, dehydrated castor-oil
68424-45-3	Fatty acids, linseed oil
	Fatty acids, safflower oil
68308-53-2	Fatty acids, soya

Monobasic Acids and Natural Oils (cont.)	
84625-38-7	Fatty acids, sunflower oil
68953-27-5	Fatty acids, sunflower-oil, conjugated
61790-12-3	Fatty acids, tall-oil
	Fatty acids, tall-oil, conjugated*
61788-66-7	Fatty acids, vegetable oil
67701-30-8	Glycerides, C16-18 and C18-unsatd.
111-14-8	Heptanoic acid
142-62-1	Hexanoic acid
512345	Hexanoic acid, 3,3,5-trimethyl-
8001-26-1	Linseed oil
68649-95-6	Linseed oil, oxidized
112-05-0	Nonanoic acid
	Oils, Cannabis*
8023-79-8	Oils, palm kernel
68132-21-8	Oils, perilla
2236997	Oils, walnut
8001-23-8	Safflower oil
8001-22-7	Soybean oil
8001-21-6	Sunflower oil
8001-20-5	Tung oil

Di and Tri Basic Acids	
88-99-3	1,2-Benzenedicarboxylic acid
121-91-5	1,3-Benzenedicarboxylic acid
1459-93-4	1,3-Benzenedicarboxylic acid, dimethyl ester
100-21-0	1,4-Benzenedicarboxylic acid
636-09-9	1,4-Benzenedicarboxylic acid, diethyl ester
120-61-6	1,4-Benzenedicarboxylic acid, dimethyl ester
528-44-9	1,2,4-Benzenetricarboxylic acid
110-15-6	Butanedioic acid
123-25-1	Butanedioic acid, diethyl ester
106-65-0	Butanedioic acid, dimethyl ester
110-17-8	2-Butenedioic acid (E)-
111-20-6	Decanedioic acid
110-40-7	Decanedioic acid, diethyl ester
106-79-6	Decanedioic acid, dimethyl ester
693-23-2	Dodecanedioic acid
61788-89-4	Fatty acids, C18-unsatd., dimers

Di and Tri Basic Acids (cont.)	
111-16-0	Heptanedioic acid
1732-08-7	Heptanedioic acid, dimethyl ester
124-04-9	Hexanedioic acid
627-93-0	Hexanedioic acid, dimethyl ester
141-28-6	Hexanedioic acid, diethyl ester
123-99-9	Nonanedioic acid
1732-10-1	Nonanedioic acid, dimethyl ester
624-17-9	Nonanedioic acid, diethyl ester
(505-48-6)	Octanedioic acid
1732-09-8	Octanedioic acid, dimethyl ester
(110-94-1)	Pentanedioic acid
1119-40-0	Pentanedioic acid, dimethyl ester
818-38-2	Pentanedioic acid, diethyl ester
1852-04-6	Undecanedioic acid

Polyols	
107-88-0	1,3-Butanediol
110-63-4	1,4-Butanediol
105-08-8	1,4-Cyclohexanedimethanol
107-21-1	1,2-Ethanediol
111-46-6	Ethanol, 2,2’-oxybis-
629-11-8	1,6-Hexanediol
144-19-4	1,3-Pentanediol, 2,2,4-trimethyl-
57-55-6	1,2-Propanediol,
115-77-5	1,3-Propanediol, 2,2-bis(hydroxymethyl)-
126-30-7	1,3-Propanediol, 2,2-dimethyl-
77-99-6	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-
77-85-0	1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-
2163-42-0	1,3-propanediol, 2-methyl
56-81-5	1,2,3-Propanetriol
25618-55-7	1,2,3-Propanetriol, homopolymer
25119-62-4	2-Propen-1-ol, polymer with ethenylbenzene

Modifiers	
110-99-6	Acetic acid, 2,2′-oxybis-
71-36-3	1-Butanol
108-93-0	Cyclohexanol
80-04-6	Cyclohexanol, 4,4′-(1-methylethylidene)bis-
112-34-5	Ethanol, 2-(2-butoxyethoxy)-
111-27-3	1-Hexanol
72318-84-4	Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane
13393-93-6	1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)-
25036-25-3	Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2,2′- [(1-methylethylidene)bis(4,1-phenyleneoxymethylene)] bis[oxirane]
68440-65-3	Siloxanes and Silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated
68957-04-0	Siloxanes and Silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated
[1]68957-06-2	Siloxanes and Silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated
[1]68037-90-1	Silsesquioxanes, Ph Pr

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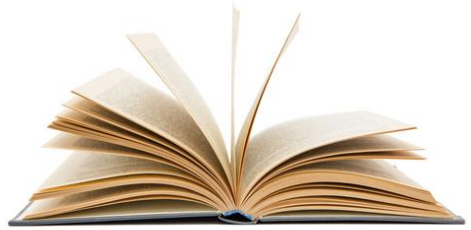
Mr Claus Urban
Global Regulatory Affairs Manager at Sika,
FEICA Polymers Requiring Registration (PRR) TTF Chair

Use of polymers in adhesives and sealants

Application of polymers in S&A

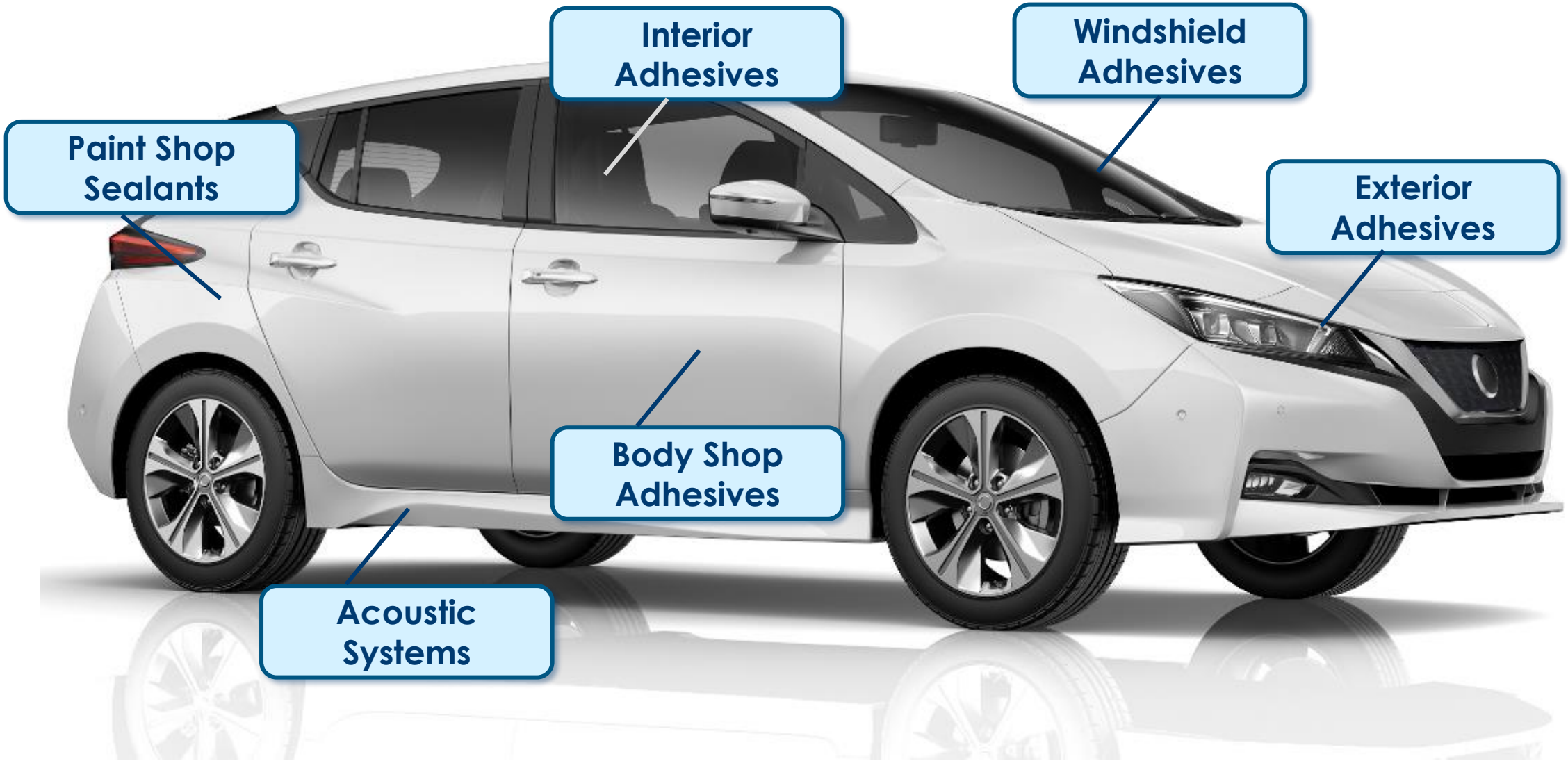
Adhesives and sealants are used in numerous applications across the industry.
Here are some examples:

- Wood & furniture industry
- Textile lamination
- Packaging
- Graphic arts
- Electronics
- White goods/sporting goods
- Construction joints
- Tile bonding
- Industrial flooring
- Wind turbines
- Automotive industry

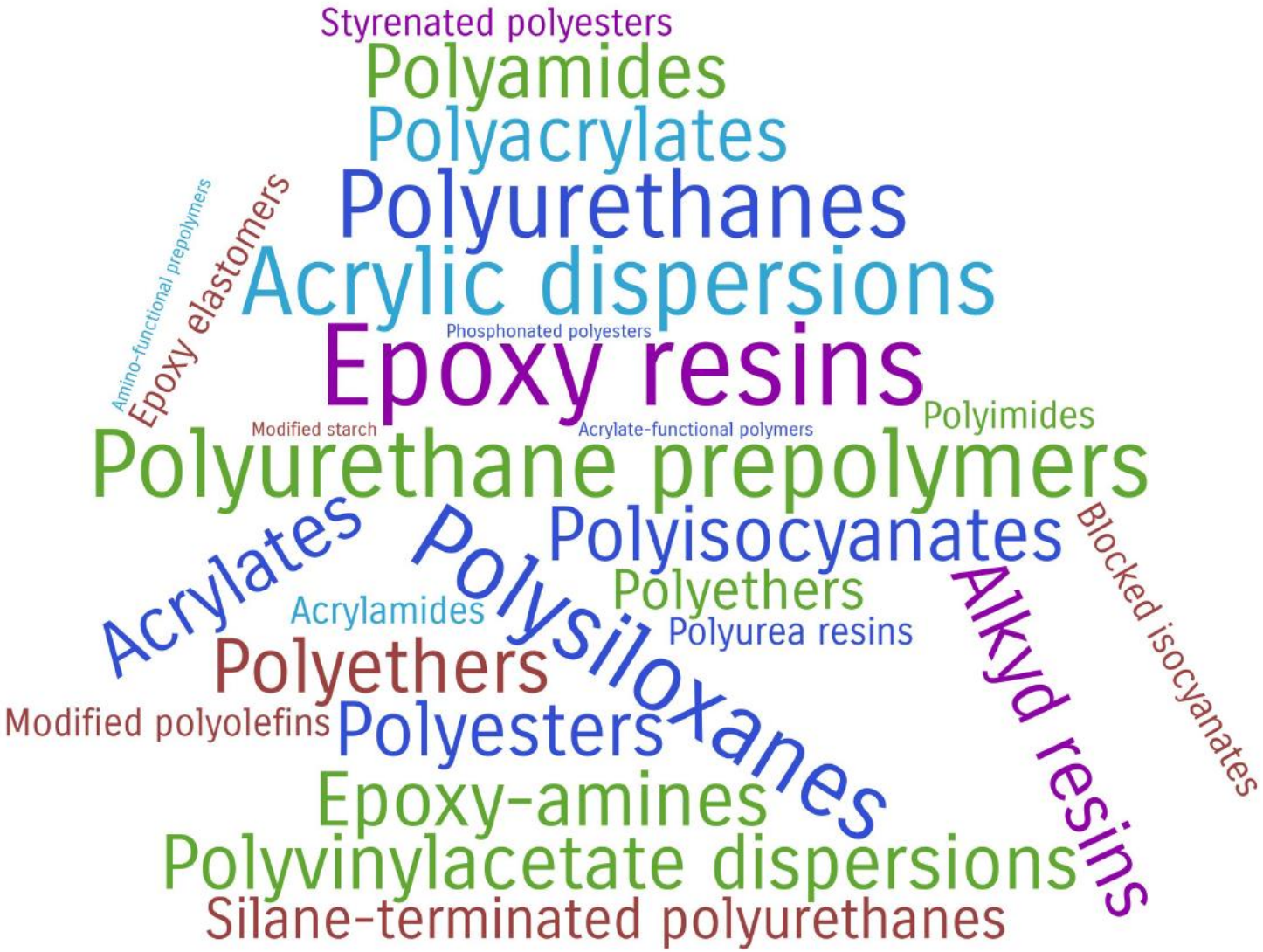


➡ **Most of these applications rely on polymers.**

Automotive bonding and sealing

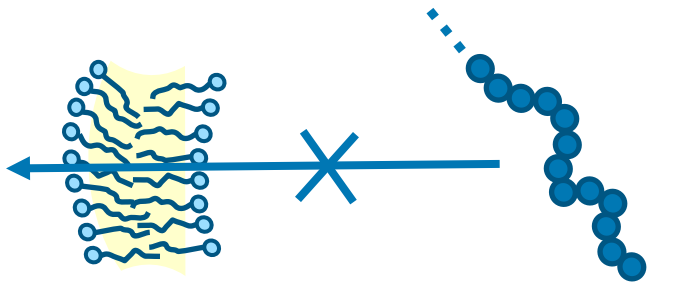


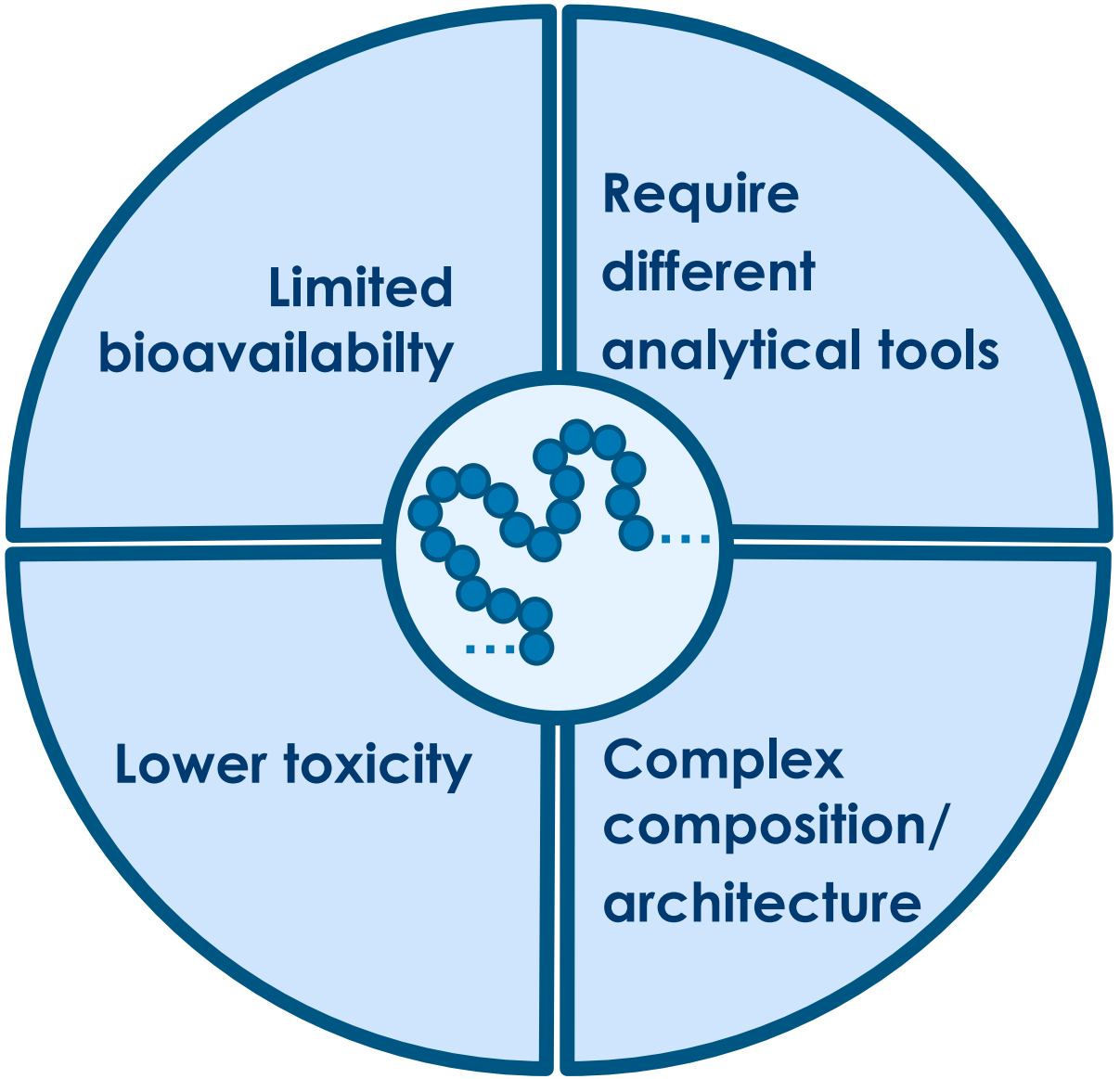
Polymers at FEICA

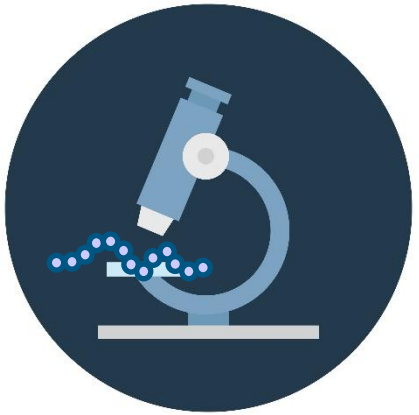


Are Polymers Different?

… compared to low-molecular-weight substances.

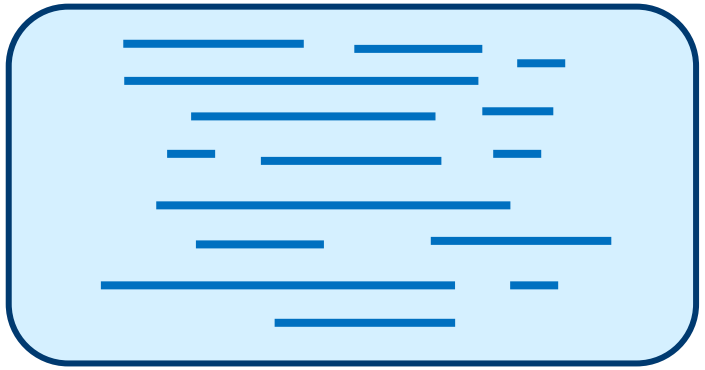






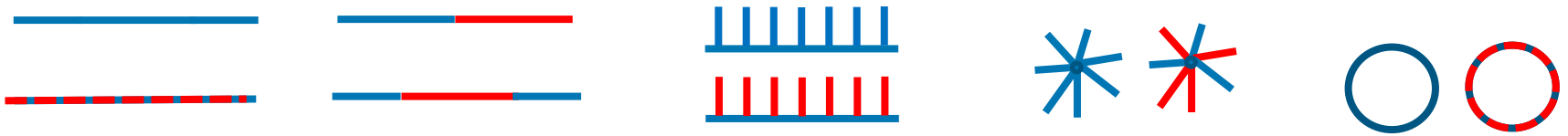
Polymer Complexity

Polymers often consist of a large number of species of different lengths (**molecular mass**):



Polymers have a molecular mass distribution → described by an *average molecular weight* ($\overline{M_n}$, $\overline{M_w}$)

In addition, there are a number polymer *architectures* (even more from combining two monomers – –):

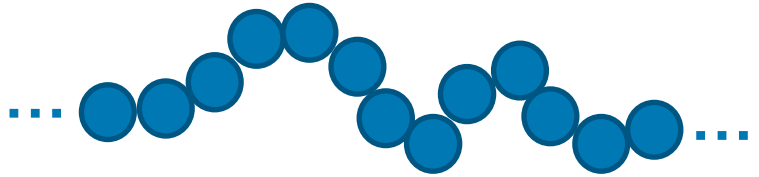


What are Polymers – in Science?

IUPAC definition:

Macromolecule:

- ‘A molecule of *high relative molecular mass*, the structure of which essentially comprises the *multiple repetition of units* derived, actually or conceptually, from molecules of low relative molecular mass.’



Polymer:

- Polymers are substances composed of macromolecules.

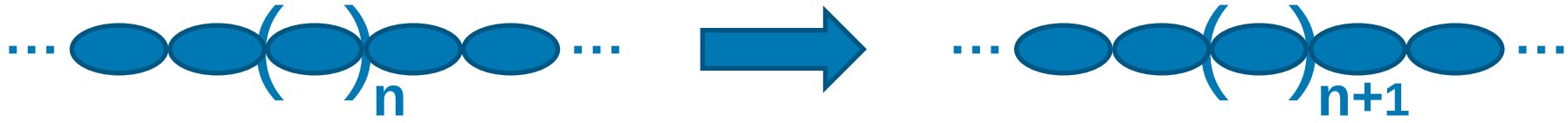
➡ Polymers basically are a ‘mixture of long molecules made of monomers’.

➡ No defined borderline between polymers and ‘non-polymers’.

What are Polymers – in Science?

Another concept for polymer used in science:

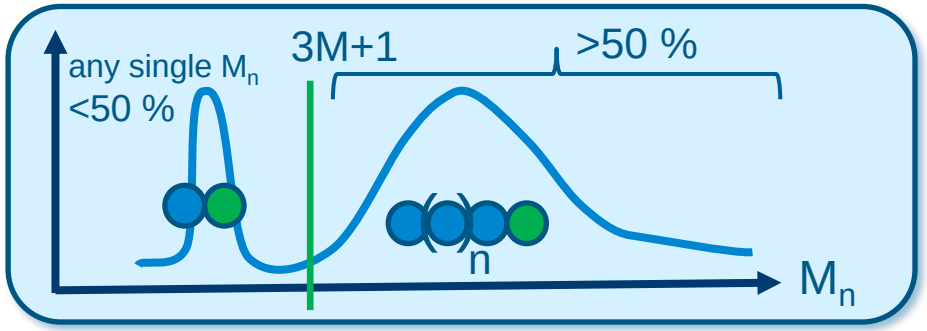
- IUPAC polymer definition plus …
- A molecule is a polymer if essential properties do not change upon addition of another monomer unit.



➡ Still no well-defined borderline between polymers and ‘non-polymers’.

What are Polymers – in Regulations?

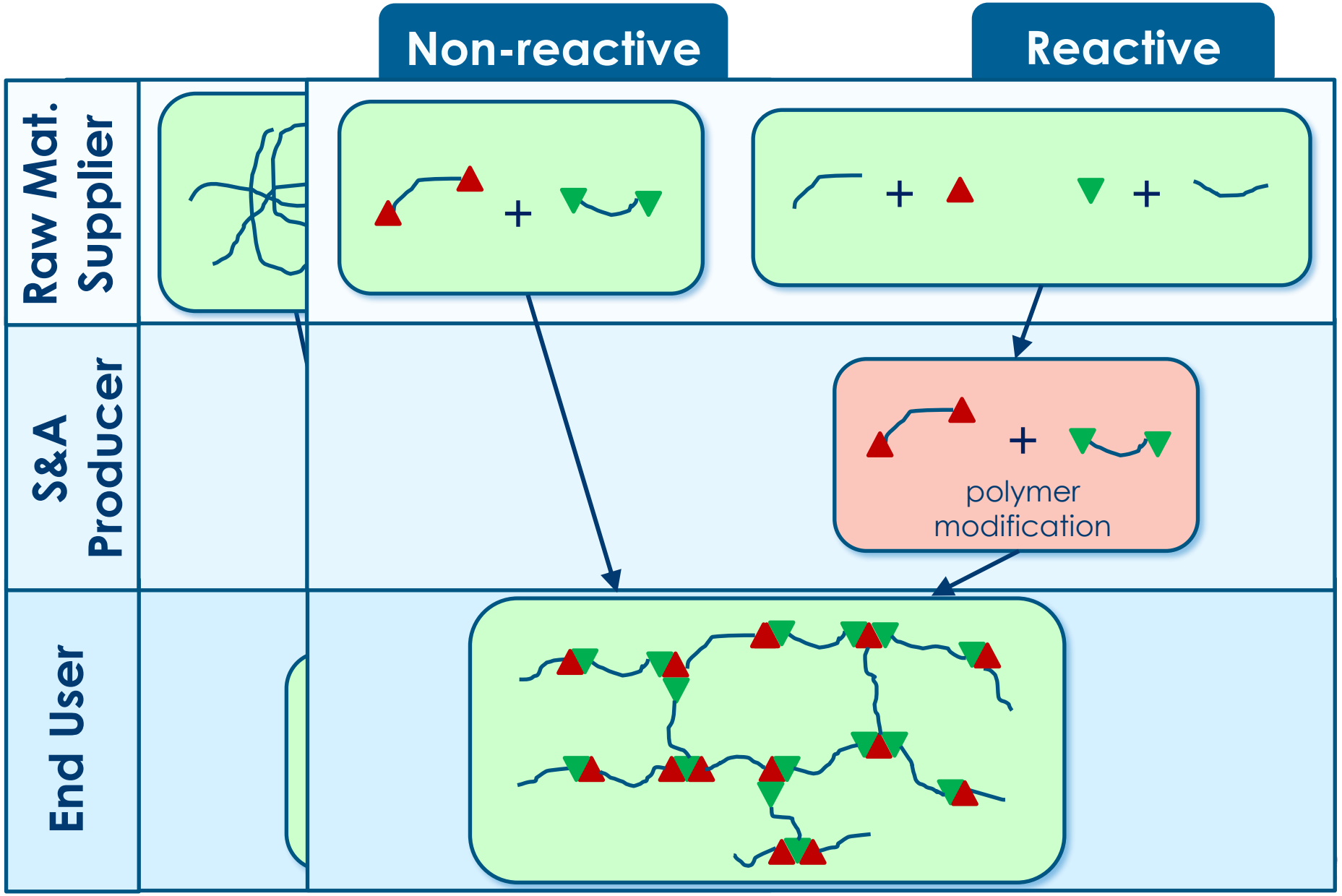
Based on the **REACH/OECD Polymer Definition** (for use in new chemicals notification procedures):



- A **polymer molecule** is a molecule consisting of at least three monomer units covalently bound to at least one other monomer unit or other reactant ('3M + 1 rule').
- A **polymer** is a substance …
  - consisting of molecules characterized by a **sequence** of one or more types of **monomer unit.**
  - Where differences in the molecular weight are primarily attributable to differences in the number of monomer units.
  - comprising **> 50 wt.-% of polymer molecules.**
  - comprising **< 50 wt.-%** of molecules **of the same molecular weight.**
  - having molecules distributed over a range of molecular weights.

„OECD 1991; amended 1993.

Polymers in Sealants and Adhesives



Summary

- Polymers are essential for the functioning of adhesives and sealants.
- Sealant and adhesive manufacturers use a large variety of different polymers.
- Polymer properties are different and often more complex than those of non-polymeric substances.
- The regulatory polymer definition is specific for the notification of new chemicals.
- Polymers manufactured or modified by sealant and adhesive manufacturers will have to be assessed regarding registration requirements (PRR criteria).

Agenda

16:00 Introduction and legal background
by Ms Paula Diaz, FEICA Regulatory Affairs Manager

16:15 Polymers regulation in the United States
by Ms Tracy Williamson (EPA), Chief, Industrial Chemistry Branch, New Chemicals Division, Office of Pollution Prevention and Toxics, U.S. EPA

16:30 Use of polymers in adhesives and sealants
by Mr Claus Urban, Global Regulatory Affairs Manager at Sika, FEICA Polymers Requiring Registration (PRR) TTF Chair

16:45 Adhesives and sealants industry perspective on the registration of polymers
by Ms Kim Suetens, Scientific and Regulatory Affairs Advisor at Soudal, FEICA Polymers Requiring Registration (PRR) TTF Vice Chair

17:10 Q&A, moderated by Ms Paula Diaz

17:30 Close of the webinar

Kim Suetens
Scientific and Regulatory Affairs Advisor at Soudal,
FEICA Polymers Requiring Registration (PRR) TTF Vice Chair

Adhesives and sealants industry perspective on the registration of polymers

Highlights for downstream users

A large number of downstream users companies:

- Will become registrants for the first time
- Are SMEs
- Might not have the expertise/resources to complete a registration dossier
- Face issues different from those of multinational chemical manufactures, such as the **need to customise polymers in order to comply with customer and regulatory requirements**

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Reasons for customisation

Modification of the polymers is necessary to:

- Achieve customer requirements
- Comply with regulatory requirements
- Provide more demanding properties in end use
- Address specific processing and performance requirements of very different application areas
- Design from/for recycling
- Support the Green Deal initiative
- …

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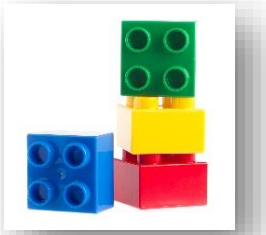
Customisation and continous improvement are key to stay competitive and respond to changing market requirements.

Effects of customisation

Many customised polymers are produced with just a few building blocks.

However, this can result in a large number of specific polymers.



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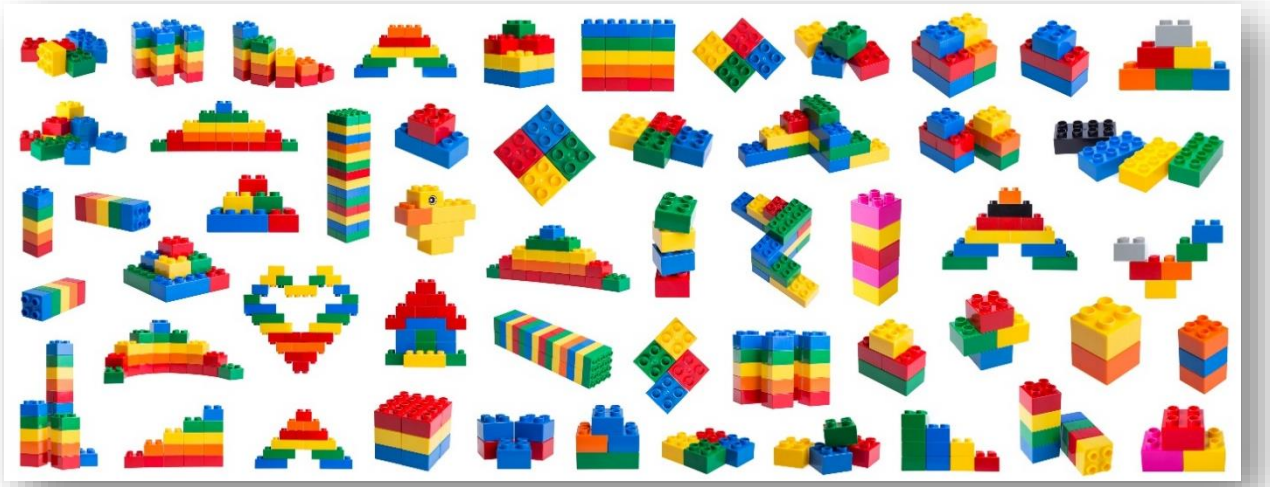

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Multiplicity of polymers

Although a very large number of individual polymers can be produced:

- the total production volume of each individual polymer is comparatively low

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Short life cycle of customised polymers

Low total production volume of an individual polymer

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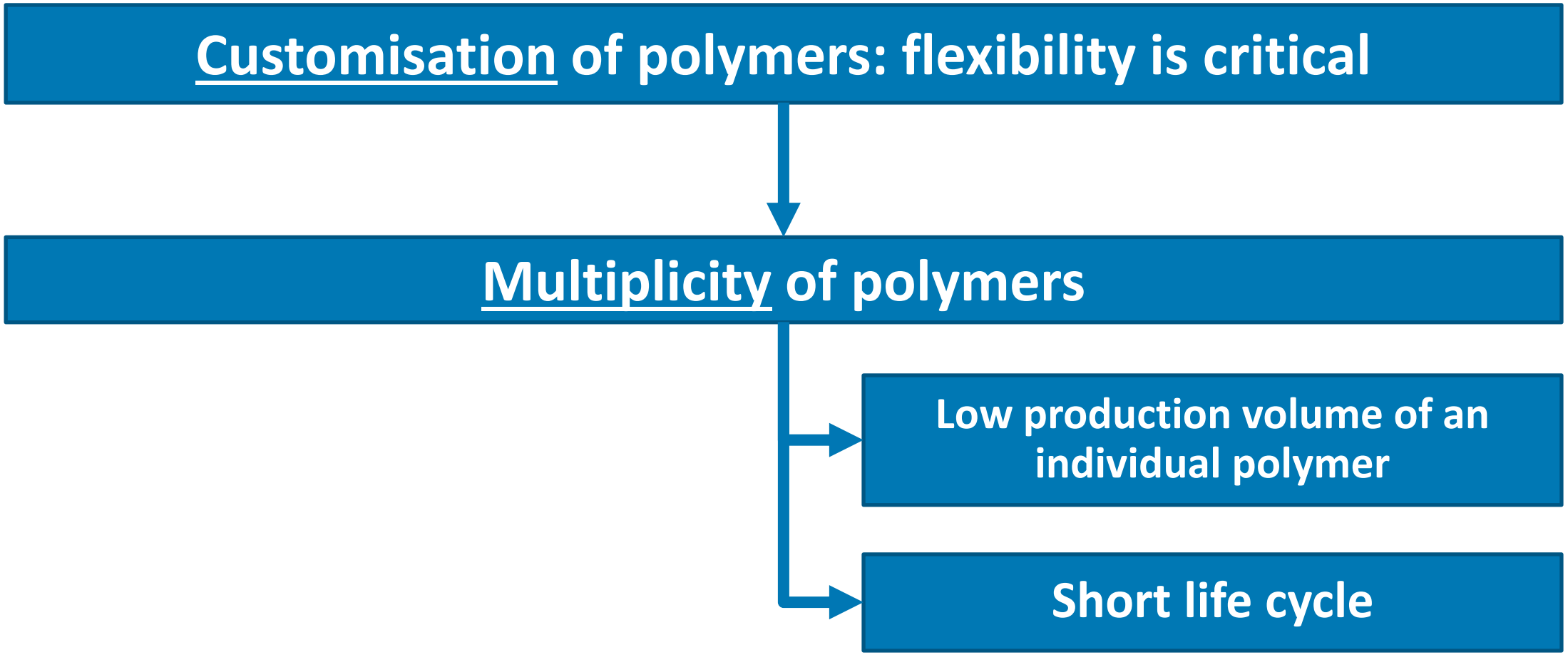
Life cycle of a single customised polymer < 3 years

Dependent on customer demands, market developments and changes in regulatory requirements

Creating innovative solutions



How could the impact of the registration of polymers be reduced?

- Wide grouping criteria
- Exposure-based exemptions (e.g., for polymeric precursors)
- Polymers of Low Concern
- Volume cutoffs

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Why grouping is relevant?

- Without grouping a huge number of polymers must be registered while the total production volume of each individual polymer is comparatively low
- Certain classes of customised polymers often have very similar structural features and hazard profiles
- Short life cycle of certain polymers: registration should not prevent formulation of short life cycle polymers
- Grouping limits the amount of animal testing

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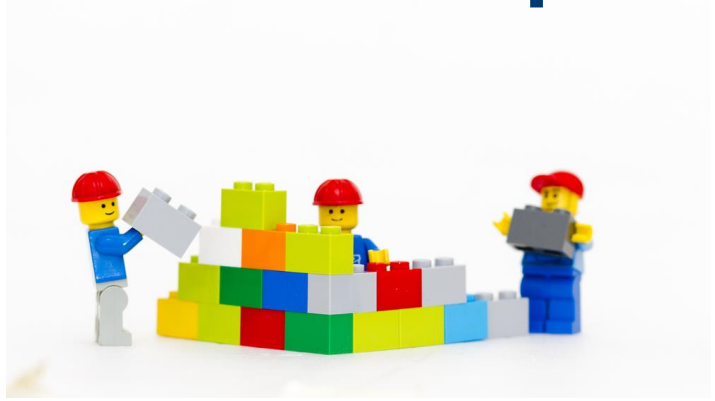
How will exposure be considered?



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Exposure….

Key considerations

- Will polymers with no or low exposure (e.g., polymeric precursors) be exempted from registration?
- Will reduced registration requirements for polymers with low-exposure hazard be foreseen instead?

Volume considerations

The toxicity of polymers in general is lower than the toxicity of non-polymeric substances.

→ Data requirements should be lower than for substances

- Cut off values?
- Tonnage bands?

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Recap

- Many **downstream users will become polymer registrants** for the first time
- **Customisation of polymers is needed** to satisfy customer and regulatory requirements
- An **easy and straightforward registration process** should be ensured **to allow the flexibility** needed to adapt polymers to market needs on short notice
- Polymers differ from non-polymers: **grouping approach**

Work in progress

- The **review of REACH** to include registration requirements will be proposed by the European Commission in **2022**
  - First outline by the end of 2021
  - Adoption of draft REACH revision by the end of 2022

- **In line with REACH objectives,** the new polymers registration scheme intends to protect **human health and the environment**, without losing the **competitiveness and innovativeness** of the European industry

Q&A

- Please use the chat box if you have a question
- Questions in the chat box will be covered as we go along

Ms Paula Diaz
FEICA
Regulatory Affairs Manager

THANK YOU

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Other interests or questions?

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