



Polymers and Monomers under REACH

**GPS and REACH Chemicals Legislation
Workshop
11 April 2013
Soporna**



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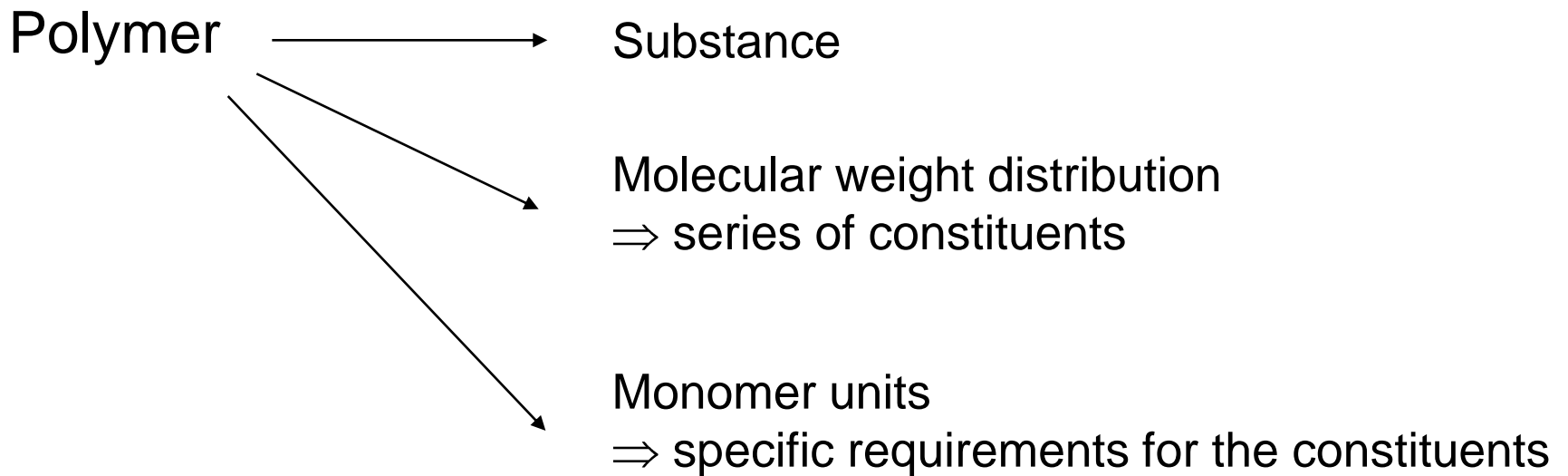
Content

- REACH: monomers and polymers
- Polymers notified under 67/548/EEC
- Post reacted polymers
- Polymers of unknown composition
- Unbound monomers
- Developments



Polymers- Terminology under REACH

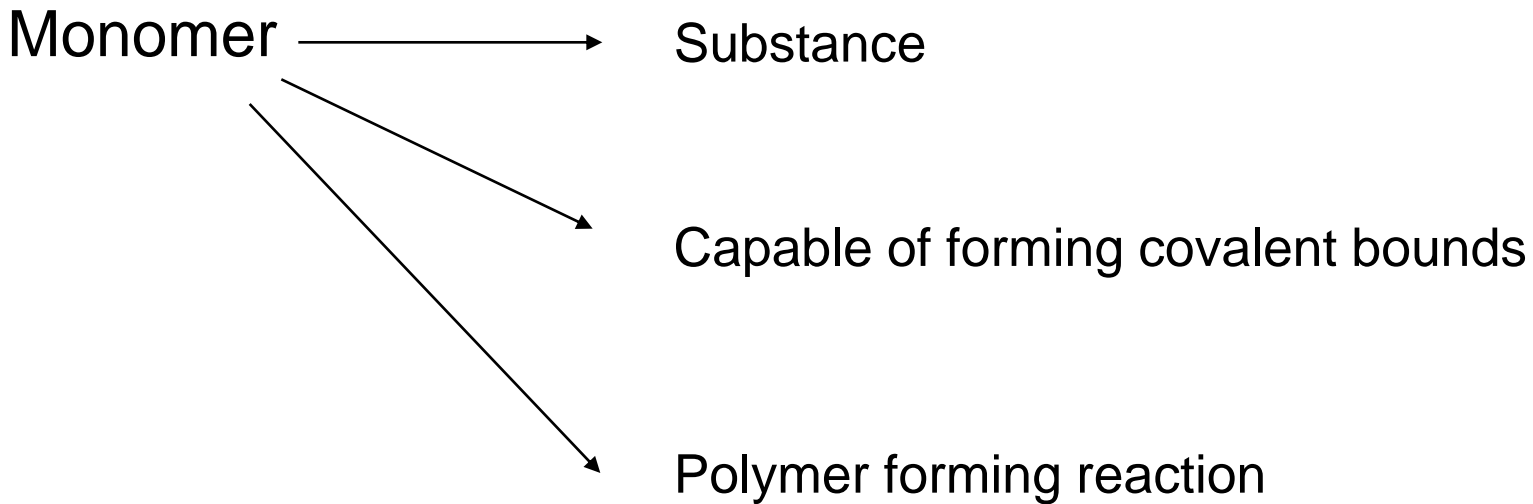
- **Polymer definition (Article 3(5))**





Monomer- Terminology under REACH

- **Monomer definition (Article 3(6))**



- **Registration required if >2% and > 1t/a**



Polymer definition

Monomer	M_1		}	Non-polymeric < 50 weight-%
Dimer	M_2 or M_1 -R			
Trimer	M_3 or M_2 -R			
Tetramer	M_4 or M_3 -R	< 50 weight-%	}	Polymeric \geq 50 weight-%
Pentamer	M_5 or M_4 -R	< 50 weight-%		
Hexamer	M_6 or M_5 -R	< 50 weight-%		
Heptamer	M_7 or M_6 -R	< 50 weight-%		
Octamer	M_8 or M_7 -R	< 50 weight-%		





Polymers and monomers under REACH

- Polymers are
 - » Substances
 - » Exempted from REACH Titles II (Registration) and VI (Evaluation)
- Monomers are
 - » Substances
 - » Intermediates
 - Non-isolated: exempted from REACH
 - On-site isolated: art 17 does *not* apply*
 - Transported isolated: art 18 does *not* apply*



» If isolated: Full registration is required



Monomers under REACH

- Intermediates
- Are manufactured in order to be transformed into another substance
- Are consumed in a chemical reaction
 - » Therefore cease to exist
 - » The newly created substance has to be registered under REACH, unless it is polymeric (exempted)

Monomer life cycle ends with polymerisation

However recent guidance from ECHA requires to include polymer uses in monomer CSA



Polymers notified according 67/548/EEC

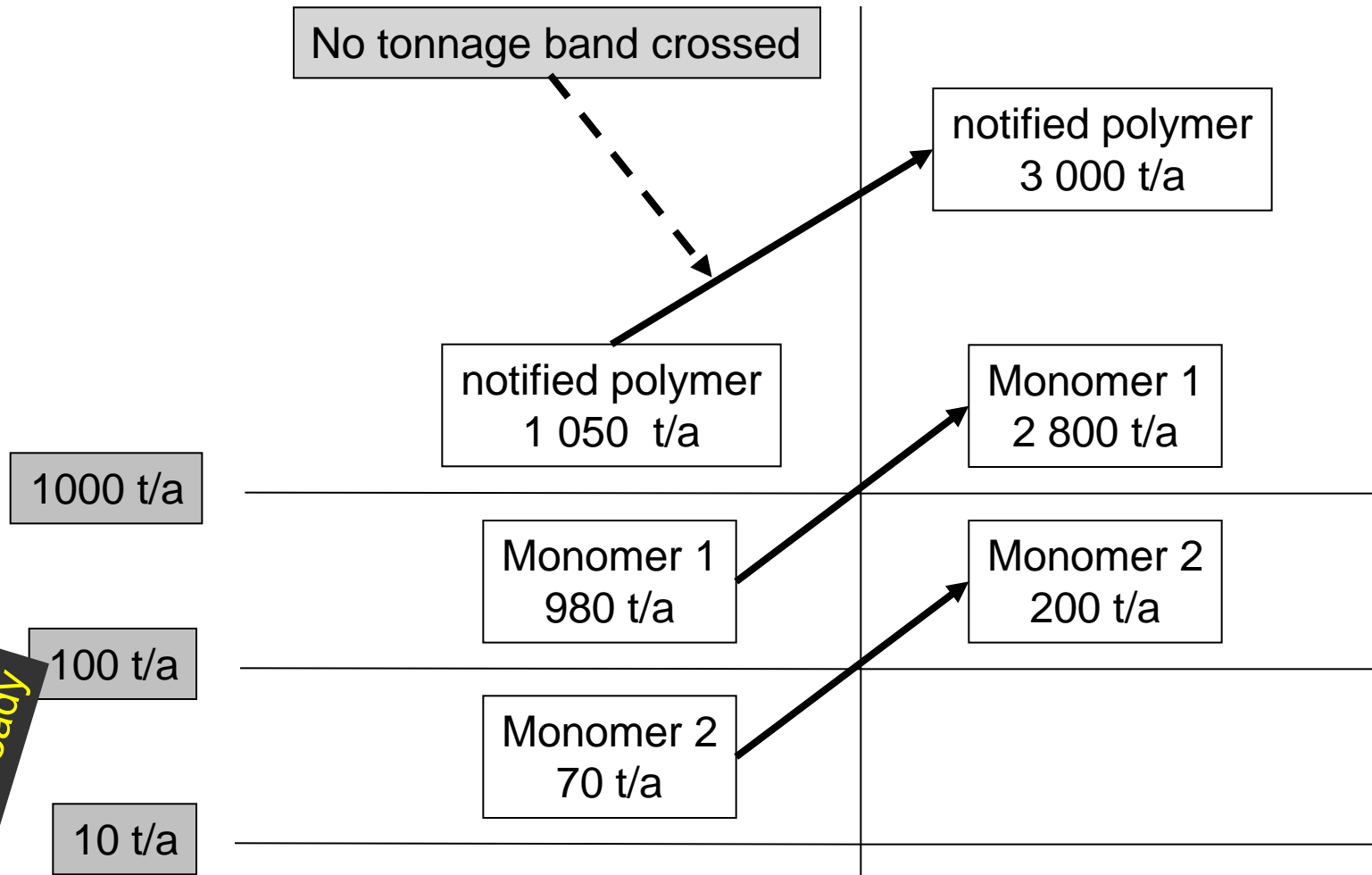
- the monomers are exempt from REACH registration,
- until the **polymer** exceeds the next tonnage threshold

In case of exceeding tonnage threshold:

- Each monomer should be registered for monomer used for the polymer tonnage
 - This could be a lower tonnage band as the polymer
 - From this moment registration follows monomer tonnage bands.
- Source: Guidance for Monomers and Polymers, 3.2.1.2, version April 2012



NOTE: "Monomer" should be read as "Monomer or other reactant".



Click when ready

Polymers registered over 1 000 t/a, never reach a next tonnage threshold →
the monomers will never need to be registered, but you can





Post reaction

- Definition:
 - » A post-reacted polymer is a polymer that, after a chemical reaction, has formed a covalent or ionic bond to another reactant
 - » Provision is, the resulting post-reactant substance meets the polymer definition, as defined in Article 3.5



Other reactant

- "Other reactant"
 - » refers to a molecule that can be **linked to** one or more sequences of **monomer units** but which **cannot be regarded as a monomer** under the relevant reaction conditions used for the polymer formation process

Source: Guidance for Monomers and Polymers



What are post-reactants?

- **Post-reactants**

- Can be linked to one or more sequences of monomer units

- Are not monomeric in nature

- **Other reactant**

- Can be linked to one or more sequences of monomer units

- Are not monomeric in nature

Conclusion:
post-reactants are "other reactants"



What are post-reactants?

• Intermediates

- Consumed in a chemical reaction
- Transformed into another substance

• Post-reactants

- Consumed in a chemical reaction
- Transformed into another substance

Conclusion:



- Post-reactants are "Intermediates"
- Article 3.15 applies



How to register post-reactants

- Post-reactants are not monomers
 - » Article 6.2 does not apply
 - Post-reactants are "other substances"
 - » Article 6.3 applies
 - If post-reactant ≥ 2 weight-% and
 - ≥ 1 tpa
- } → Registration
- What registration scheme to follow?
 - Post-reactants are intermediates
 - » Non-isolated post-reactant: article 2.1(c) applies: exempted
 - » On-site isolated post-reactant: article 17 applies
 - » Transported isolated post-reactant: article 18 applies



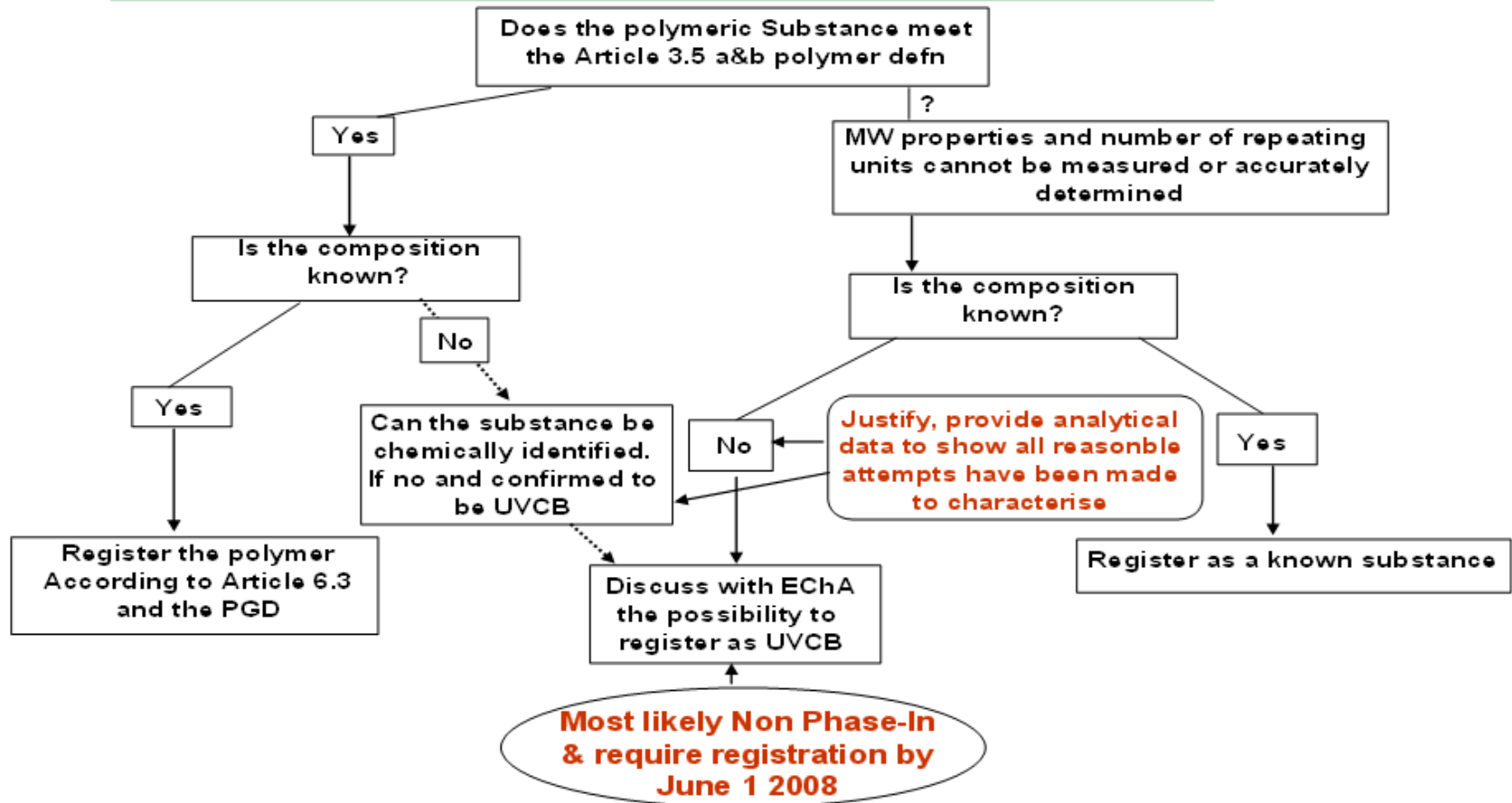
Polymer essentials

- Conformance with the OECD polymer definition
- The identity and concentration of each monomer or other reactant the polymer contains in combined/reacted form
- If this is impossible, determine whether the substance can be treated and registered as a UVCB
 - » even if the substance does not have an EINECS number

UVCB is a substance of Unknown or Variable composition, Complex reaction products or Biological material



Polymers of Unknown Composition





Impurities

- REACH article 3.1:
 - a substance = the substance + any impurity
- Framework for Substance Identification in REACH
 - 2.2 defines an impurity as:
 - "An **unintended constituent** present in a substance as produced.
 - **It may originate from the starting materials**
 - or
 - be the result of secondary
 - or
 - **incomplete reactions** during the production process.
 - While it is present in the final substance it was not intentionally added."





Unbound Monomer in a Polymer

- Its presence:
 - » Is unintended
 - » originates from the starting materials
 - » Is the result of an incomplete reaction
- Conclusion:
 - » An unbound monomer is an impurity



Monomer units and REACH

- REACH Article 3.5:
 - » "... a 'monomer unit' means the reacted form of a monomer substance in a polymer"
 - » Unbound monomers are not monomer units
- REACH article 6.3:
 - » Registration of the monomers if 2 conditions are fulfilled:
 - Monomers present at $\geq 2\%$ "in the form of **monomer units**"
 - The total quantity is ≥ 1 tpa
 - » As unbound monomers are not monomer units, article 6.3 does not apply
- If article 6.3 does not apply, registration of the unbound monomer is not needed





Unbound monomers and REACH

- Conclusions:
 - » An unbound monomer in a polymer is an impurity
 - Unbound monomers are an integral part of the polymer
 - » A monomer is not a monomer unit
 - » Article 6.3 does not apply to unbound monomers
 - » Title II on registrations does not apply to polymers
 - » Unbound monomers do *not* need to be registered
 - » Unbound monomers do *not* need to be incorporated in the registration dossier of bound monomers

Recent Commission interpretation of Court Case is that unbound and bound monomer need to be considered for registration



Natural Polymers

ECHA guidance 3.2.1.3:

- Result of a polymerisation in nature
- Are exempted from registration
- Chemically modified natural polymers are exempted as well
- Monomeric substances in natural polymers are non-isolated intermediates and therefore no registration
- Substances for modifying the natural polymers needs registration
- If building blocks are not scientifically identified, the substance must be regarded as UVCB





Recycled polymers

- Exempted from registration provided:
 - » The substances constituting the recycled polymer have been registered and the information is available with the recycling company
 - » The information does not need to come from an actor in the same supply chain



Developments

- In June 2011, tender for review registration requirements on polymers
 - Industry did make a bidbook
 - Study granted to RPA

- Industry started own polymer screening project
 - Over 500 polymers
 - However not representative
 - Not all industry groups represented
 - Overrepresentation hazardous polymers due to CLP notifications
 - Substance identity unclear
 - Unclear what is hazard causing: monomer, ingredients, polymer



Developments (2)

- Commission study not published yet
 - » Not part of 2012 REACH review
- Industry screening result not published as data is not representative

How will this develop?

- Next (2018) review of REACH?
- Inclusion certain categories of polymers?
- Monomer life cycle does not end with polymerisation



Useful links

- ECHA guidance on monomers and polymers:

<http://echa.europa.eu/guidance-documents/guidance-on-reach>

- Cefic guidance on monomers and polymers:

<http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/>

- Cefic REACH Implementation Workshops:

<http://www.cefic.org/Industry-support/Implementing-reach/Information-and-Experience-Exchange-Forum/>





Thank You!

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