Registration of Monomers in Polymers and Polymers Requiring Registration

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Keller & Heckman

Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few U.S.-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.

Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.

Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.

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Ales Bartl

Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products and product and food safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues. Ales also advises on product recalls and withdrawals.

Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).

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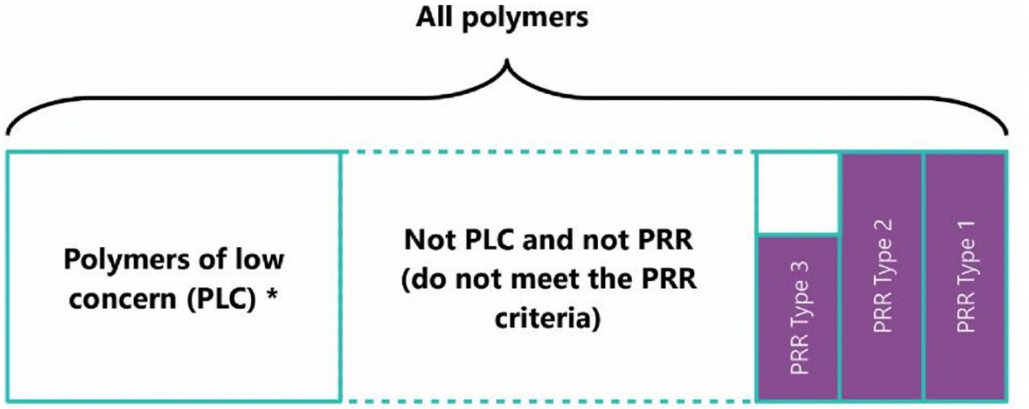
Developments on Polymers Requiring Registration

CASG-Polymers Subgroup

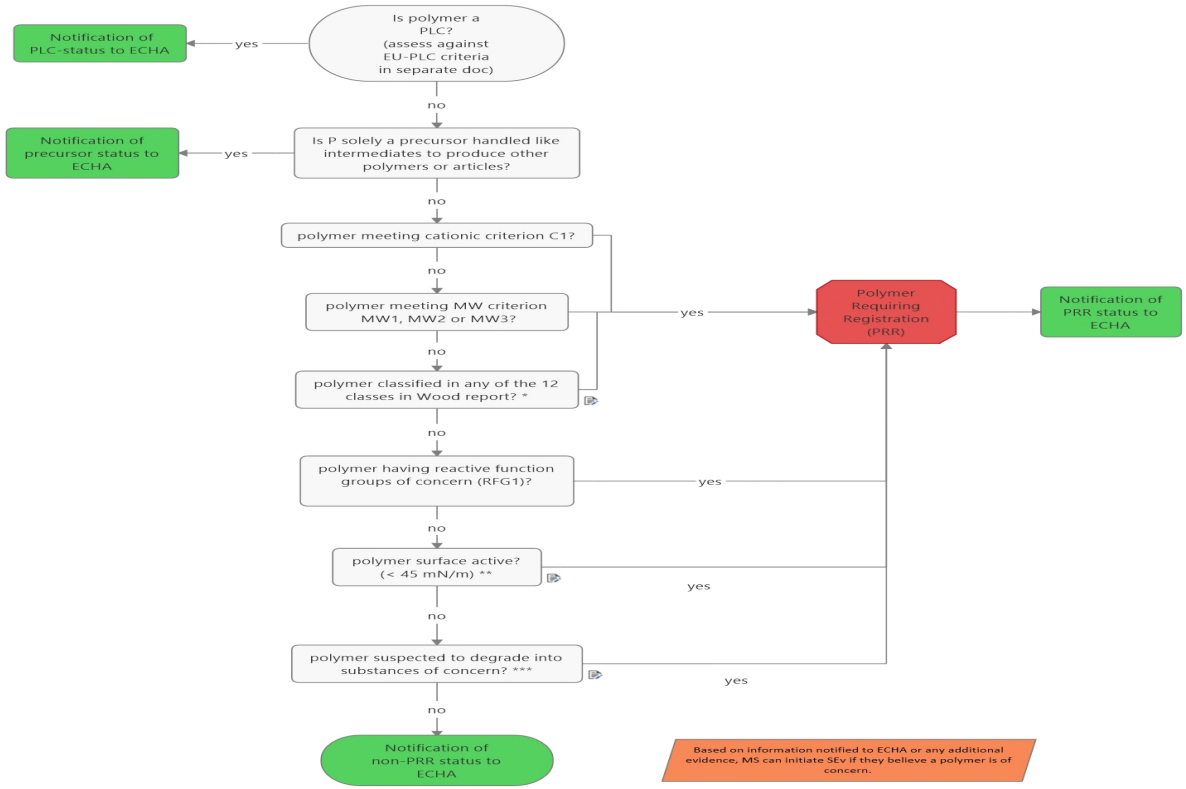
- Commission has established a subgroup of experts from EU member states (CASG-Polymers) to lead the work to develop a proposal for registration of Polymers Requiring Registration (PRR) under REACH
- Subgroup provides advice on the following policy issues:
  - **Which type of classes of polymers merit registration** for the benefit of further assessment and risk management
  - **What information requirements** should be proposed for registration
  - **Options to be considered** in the context of an **impact assessment** planned for the end of 2022
  - **The need for testing on animals as a last resort** and for the use of non-animal methods wherever possible to generate new data

Dividing Up the Universe of Polymers – Wood Consultancy Proposal



Only purple-shaded areas are polymers requiring registration (PRR)
Type 1: < 1000 Da – Data as for non-polymers
Type 2: 1000-10,000 Da – Testing strategy (reduced testing)
Type 3: > 10,000 Da – Only PRR if include certain structural features e.g. cationicity or reactive functional groups
* Criteria to identify PLC are considered to be already well accepted (e.g. EC 2015, OECD 2009)

PRR-Identification Flowchart – Update 8 June 2021



Commission Proposal for an EU-Definition of Polymers of Low Concern (PLC): Version 8 June 2021

- 1) Inclusion criterion for approved polyesters
  - Develop a dynamic EU-polyester list that is built on the AUS reactants lists, minus reactants that Canadian Experts advised to take off the list; such an EU-list could either be added to Annex V of REACH or be handled in a separate Annex
  - Polymers built from reactants on this list of allowed polyester reactants can qualify as PLC also in the EU; no other criteria need to be compared against
- 2) Molecular weight Criterion
  - Same as US except per-fluorinated polymers with MWn ≤ 1500 Da cannot qualify as PLC

Proposal for an EU-Definition of PLC (2)

- 3) Qualification as PLC based on RFGs for polymers MWn ≥ 1000 Da
  - The following specifications regarding the content of Reactive Functional Groups (RFGs) should be met for a polymer to qualify as PLC:
    - Polymers containing only low-concern functional groups can qualify as PLC
    - If the polymer contains only moderate-concern groups, the groups should have a Functional Group Equivalent Weight (FGEW) above 1,000 Da each and combined FGEW over 1,000 Da in order to qualify a PLC
    - If the polymer contains high-concern and moderate-concern groups (or high-concern groups only), the combined FGEW of these groups should be over 5,000 Da. Furthermore, each high-concern group should have a FGEW over 5,000 Da and each moderate-concern group should have a FGEW over 1,000 Da in order to qualify as PLC
- 4) Exclusion based on high water-absorption capacity
  - Same as US except highly water-absorbing polymer must contain particles with a particle size <10 micrometres (microns)

Exclusion Criteria Based on Composition, Ionicity, Degradation, and Hazard Classification

EU	Ionicity criteria	Elemental limitations	Degradation criteria	Hazard criteria
	A cationic polymer or a polymer that is reasonably expected to become cationic in a natural environment.	A polymer that has, as an integral part of its composition, only one or none of the following atomic elements: carbon, hydrogen, nitrogen, oxygen, silicon and sulphur, or that has: (a) any atomic elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine covalently bound to carbon; (b) any monoatomic counterions other than chlorine ion, bromine ion, iodine ion, sodium ion, divalent magnesium, trivalent aluminium, potassium ion or divalent calcium; or (c) 0.2% or more by weight of any atomic element or combination of the following atomic elements: lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium.	A polymer that is designed, or can be expected, to substantially degrade, decompose or depolymerise into substances having one or more of the hazard classifications listed under Hazard criteria in the right column.	A polymer cannot qualify as a PLC if it is classified as a hazardous chemical according to Regulation 1272/2008/EU on Classification and Labelling of Chemicals (health and environmental criteria) in one or more of the following hazard classes: (Acute Tox. 1 to Acute Tox. 4); (Muta. 1A, Muta. 1B or Muta. 2); (Carc. 1A, Carc. 1B or Carc. 2); (Repr. 1A, Repr. 1B, Repr. 2 or Lact.); (Asp. Tox. 1); (Resp. Sens. 1, 1A or 1B); (Skin Sens. 1, 1A or 1B); (STOT SE1 to SE3); (STOT RE 1 and STOT RE 2); (Eye Dam. 1 or Skin Corr. 1, 1A, 1B or 1C); (Aquatic Acute 1, Aquatic Chronic 1 to 4). Under the Chemicals Strategy, work is ongoing to add new hazard classes to CLP for substances that are ED, PBT, vPvB, PMT and vPvM. Once those new classes for critical hazards have been added to CLP, they would also be added to the hazard classes which would prevent a polymer from qualifying as PLC.

ECHA "Thought Starter" on PRRs

- Woods Consultancy estimated that 33,000 polymers and 11,000 unique polymers would require registration
- Need for developing criteria to establish which PRR should be jointly register as one "PRR Substance"
- When a PRR is available in three different Types which differ only in their number average molecular weight (<1000 Da; 1000-10,000 Da; >10,000 Da)
  - All types would register jointly as one PRR Substance
  - Individual registrations would use the Type as the basis for adaptations according to (a suitably altered) Annex XI which provides Type-specific adaptations for PRR Substances

Criteria for Establishing Which PRRs Can Be Jointly Registered as One PRR Substance

- ECHA proposes that the grouping of polymers into one PRR Substance is based on the identity of the starting materials contributing to at least 2% of the polymerised part of the polymers
- The use of different reactants contributing to less than 2% of the polymerised part, if any, is allowed
  - The ratio of reactants can vary
  - The impurity profile can vary
  - The molecular weight can vary
  - The monomer(s) ordering and tacticity can vary

Polymerisation Type, Manufacturing Process

- For a given (set of) monomer(s) and any other reactant, the manufacturing conditions may be tailored to obtain polymers with, for instance, different backbones (e.g., linear vs. branched), monomer ordering (e.g., alternating vs. random vs. block copolymers), tacticity (e.g., atactic vs. isotactic vs. syndiotactic) and end groups (e.g., polymers terminated with only one of the reacted monomer)
- Objective criteria may be considered to decide if polymers displaying such structural differences can be registered as one PRR Substance; at the outset, however, it cannot be assumed that the polymers will have the same or related hazard properties

Naming Polymers

- Polymer nomenclature should comprise the general rules for naming UVCB substances and be structured around information on the source materials and the process as a baseline
- The polymer type (e.g., specification of the backbone type and the type of monomer sequence in the polymer (random, alternating, block…)) may need to be specified at the level of the name, if relevant
- The ‘2% rule’ is proposed to be maintained for naming purposes
- The distribution of the molecular weight is expected to be characterized through the documentation of at least of Mn, Mw and the corresponding polydispersity
- The structure of the constituents in the polymerized part needs to be represented; the representation needs to display the monomer units, any other reactant contributing to the polymer constituents, the backbone type, sequence type, and the terminal groups

Member State Reaction

- France wants notification of the PRR / non-PRR status for all polymers which could include minimum information about the polymers as for example name, composition, tonnage band, molecular weight range, dispersity, names of the (co)-monomer(s), and degree of crosslinking
- Germany wants consideration of degradation into bioavailable fragments and separate consideration of micro-scale polymers
- Denmark believes surface activity is important
- Sweden also favors notification of the PRR / non-PRR status for all polymers, separate consideration of micro-scale polymers, and consideration of degradation potential

ECHA Board of Appeal Cases on Monomers in Polymers

BoA on Monomer Registration: A-001-2020 of 29 June 2021

- There is a distinction between unreacted monomers (subject to the 'normal' registration) and reacted monomers as substances incorporated in polymers after the polymerisation, which are subject to the registration obligation under Article 6(3)
- After polymerisation, a monomer ceases to exist as a substance on its own and is transformed into a new substance, the polymer; no information on exposure to the monomer after polymerisation is necessary under Article 14(1)
- In the case at hand the registrant used Annex XI exposure adaptation because: the life-cycle ended before the polymers were imported and that, therefore, the exposure 'is zero'
- The BoA: in order to rely on an adaptation under Section 3 of Annex XI, a thorough and rigorous exposure assessment of potential exposure to the monomer as an unreacted monomer in, or as a degradation product of, polymer, must be provided
- It is the responsibility of the registrant of a monomer incorporated in a polymer to demonstrate that the monomer does not pose a risk to human health and the environment due to its presence as an unreacted monomer in a polymer, or as a transformation or degradation product of that polymer

BoA on Monomer Evaluation: A-006-2016

- Article 2(9) of the REACH Regulation exempts polymers from registration and evaluation
- However, ECHA has the power to request information under Article 46 (substance evaluation) on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers
- However, if this information can only be provided by downstream users, it cannot be required by ECHA

Final Thoughts

Please join us at 1:00 PM Eastern U.S.
Wednesday, July 21, 2021
www.khlaw.com/OSHA3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, August 18, 2021
www.khlaw.com/TSCA3030

Please join us at 1:35 PM Eastern U.S.
Wednesday, September 15, 2021
www.khlaw.com/REACH-3030

Thank You

NEXT REACH 30/30

September 15, 2021

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