



Update on Polymers Requiring Registration + Enforcement Roundtable

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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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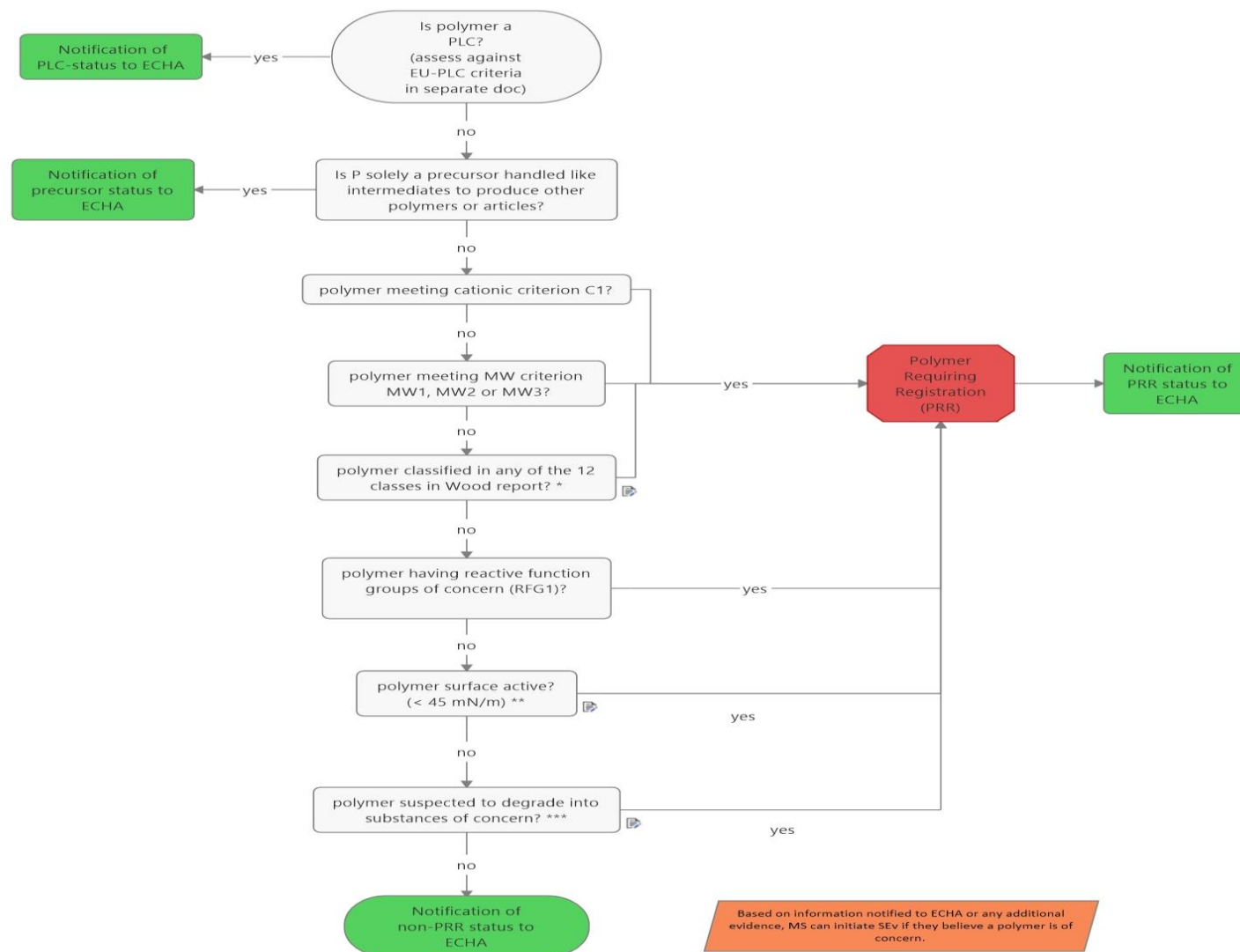
I. Update on Polymers Requiring Registration

Recap (1): July 2021 REACH 30/30



- ◆ 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
- ◆ Main activity to-date -- Working to Develop an EU definition of Polymers of Low Concern (PLC)

Recap(2): PRR-Identification flowchart – 8 June 2021 Version



Recap (3)

- ◆ As there are a large number of polymers that will require registration (tens of thousands), a strategy is needed on how to group polymers
- ◆ European Chemicals Agency (ECHA) proposed that the grouping of polymers be based on the identity of the starting materials contributing to at least 2% of the polymerized part of the polymers
- ◆ The use of different reactants contributing to less than 2% of the polymerized 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
- ◆ Several Member States want notification of the PRR/non-PRR status for all polymers which could include minimum information about the polymers, for example name, composition, tonnage band, molecular weight range, dispersity, names of the (co)-monomer(s), and degree of crosslinking

Recent Developments (1)

- ◆ The CASG-Polymers was supposed to disband on 31 December 2021, but given the number of open issues the Commission has extended the mandate until 31 December 2022
- ◆ This means a legislative proposal will not issue until 2023
- ◆ Although much remains to be decided certain concepts already appear to have the consensus of the Authorities
 - ◇ There will be a notification process similar to pre-registration, but far more information will be required.
 - ◇ Both PRR and polymers exempt from registration will need to be notified to the ECHA
 - ◇ Chemical identity of polymers will need to be defined in greater detail than simply by CAS Number to facilitate data sharing
 - ◇ Certain polymers will be exempt from registration because they meet the criteria for polymers of low concern, however, these criteria will be similar but not as inclusive as in other countries

Recent Developments (2)

For example, fluorinated polymers and water absorbing polymers will never qualify as PLC. There is also likely to be one oligomer content limitation (2% oligomer content of MW < 500 Da and less than 5% oligomer content) of MW < 1,000 Da) for all polymers with an MW > 1000 Da rather than the two tiers under the TSCA Polymer Exemption

- ◆ It appears that the 2% rule likely will not apply if the minor monomer/reactant is a chemical of concern
- ◆ Grouping of polymers will be encouraged; however, the opportunities for grouping are likely to be limited
- ◆ Polymers with varying molecular weight will be registered as a single polymer. The data will be developed on the worst case, presumably the polymer with the lowest molecular weight
- ◆ Data requirements will depend on tonnage with more data required at the higher tonnage bands

Recent Developments (3)

- ◆ Grouping of polymers will be based on chemical composition rather than uses and exposure
- ◆ Grouping based on hazardous properties is rejected
- ◆ Higher MW polymers are in general less hazardous than non-polymers; hence they will be subject to reduced standard information requirements. However, screening level tests will be required to confirm low hazard
- ◆ Environmental degradation and release of substances of concern is an exception to the general principle that high MW polymers are less hazardous. Hence methodology will need to be developed on how to assess environmental stability, degradability and release of substances of concern

Notification of Polymers

Two options are being considered:

- ◆ **Option 1**

- ◆ Minimal information: Substance identity; tonnage band

- ◆ **Option 2**

- ◆ More detailed information. Option 1 plus:

- Chemical composition of polymer (incl. Substance ID of the monomers and other reactants, oligomer content, content of unreacted monomers)
- Content of functional groups
- Structure of the polymer
- Basic physicochemical data
- Processing conditions in case of precursor status

- ◆ It appears that Option 2 is currently favored by the Authorities

II. High-level roundtable of the EU's Chemicals Strategy for Sustainability ('CSS')

Roundtable for CSS: What is it?

- ◆ Set up by the Commission
- ◆ 32 representatives, including:
 - ◇ Industry associations: Cefic, SMEunited, Cosmetics Europe, Eurometaux and Aise.
 - ◇ Industry: Henkel, Covestro, Solvay, Corbion and Coop Denmark.
- ◆ Goal:
 - ◇ Advice on implementation of CSS
 - ◇ Act as ambassadors of the CSS

First Action: REACH Enforcement



- ◆ First meeting after the inaugural meeting was held on November 25, 2021 and focused on enforcement
- ◆ To implement the "zero tolerance approach to non-compliance" goal of CSS
- ◆ As a background, the Commission has already announced:
 - ◇ Strict enforcement of 'no data, no market' (revocation of registration numbers)
 - ◇ Expanding the role of Echa's enforcement forum (coordination of enforcement authorities, including IT enforcement platforms and customs authorities)
 - ◇ Possible funding and HR assistance for national authorities through ECHA enforcement forum

Whistle-Blowing

- ◆ "Whistle-blowing mechanism" for businesses and their employees to flag illegal products from competitors or their own companies
- ◆ Strongly supported by industry representatives in the Roundtable
- ◆ SMEs: concerned that the system could be open to abuse, with large industry "policing" smaller rivals. It may undermine trust
- ◆ To address these concerns: there should be a clear process that allows companies to defend themselves and filters out vexatious complaints

Collective Redress

- ◆ Empowering consumer organizations to become "market watchdogs" for chemicals (direct reporting to EU and national authorities of suspected infringements)
- ◆ Support to develop their capacities for collective redress actions related to breaches of EU chemicals legislation
- ◆ Recent Directive 2020/1828 on representative actions for the protection of the collective interests of consumers:
 - ◇ Applicable to sectorial EU legislation and CLP at the moment (extend to REACH?)

Online Sales

- ◆ Focus: direct purchase by consumers and end users via online platforms outside the EU
- ◆ Goal: online platforms must be held liable under certain circumstances and have clear obligations (to be more transparent on trader and product information)
- ◆ The draft Digital Services Act requires platforms to verify information from traders so only legitimate traders reach consumers – chemicals to be aligned

Testing Capacities

- ◆ Goal: Prepare for enforcement of new restrictions
- ◆ Commission to develop harmonized and standardized control test methods
- ◆ Commission to ensure (funding + infrastructure development)
 - ◆ Sufficient lab capacity (including non-EU capacities)
 - ◆ Sufficient resources

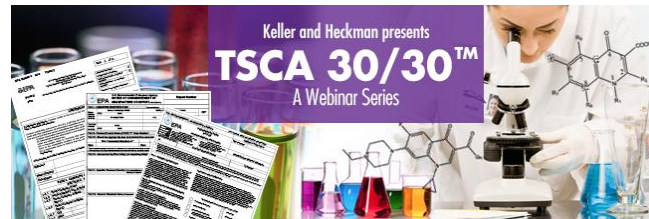
Other Recommendations From the Roundtable



- ◆ Harmonized level of sanctions across all Member States;
(amount of fines + HR proportionate to the size of the chemicals market)
- ◆ Inspection and compliance check fees imposed on non-compliant substances, dossiers or product
- ◆ Publicise non-compliant companies
- ◆ Goal: the cost of compliance must not be more than the costs of non-compliance



Please join us at 1:35 PM Eastern US
Wednesday, February 9, 2022
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern US
Wednesday, January 12, 2022
www.khlaw.com/TSCA3030



Please join us at 1:00 PM Eastern US
Wednesday, December 15, 2021
www.khlaw.com/OSHA3030



Please join us at 3:00 PM Eastern US Tomorrow,
Thursday, December 9, 2021
www.khlaw.com/events/ada-website-accessibility-lawsuits-current-legal-landscape-and-risk-mitigation-strategies

Thank You

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