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Webex

Concerns: **High-level summary of COM-ECHA proposal for registration
of polymers**

Agenda Point: **4**

High-level summary of COM-ECHA proposal for registration of polymers

The proposal for the registration process of polymers can be divided into the following main steps, illustrated in more detail by Figure 1:

- Assessment of PRR/non-PRR/Polymeric precursor status of all polymers put on the market
- Notification of polymers
- Grouping of polymers for registration and formation of joint submissions
- Registration of polymers meeting PRR criteria
- Regulatory work by ECHA

Assessment of polymer status

The first step in the registration of polymers is the assessment of each polymer manufactured or imported in the EEA at or above 1 tpa against the PRR criteria¹.

Notification of polymers

The obligation to notify applies to all polymers as defined by REACH Art. 3(1) and 3(5) from the threshold of 1 tpa. Through notification, an inventory will be established on the amount and identity of polymers on the European market and their status (PRR/non-PRR/Precursor). The information collected via the notifications supports the authorities in the definition of criteria for grouping of polymers for registration and, to the extent made public, helps companies in the forming of joint registrations. The notifications can also serve authorities in checking process conditions of polymer precursors and to verify the conclusion on the polymer status (PRR/non-PRR/Precursor).

Annex 1 lists the type of information that is expected to be submitted in a notification of a polymer assessed to be PRR. The requirements for polymers of other status may be reduced, while still allowing the verification of the outcome of the PRR assessment.

Following notification, ECHA will use the information collected in notifications for polymers of PRR status to develop and propose a set of clear and objective (chemical and where possible phys-chem) criteria that can be used to group polymers for registration. The criteria will be made available in the form of an implementing regulation and ECHA Guidance.

ECHA will also publish the information from notifications on its website, to the extent where commercial interests of notifiers are deemed not to be compromised. Confidentiality requests for information within a notification will be assessed within the regime established in REACH (*mutatis mutandi*, Articles 118 and 119²). Based on the information contained in the notifications, ECHA will derive and publish systematic names for the notified polymers to facilitate discussions among manufacturers/importers of the same and similar polymers.

The public inventory of notified polymers will also be useful when new actors/polymers enter the market, as they can see whether the same and similar polymers have been previously notified and are expected to be registered.

Grouping of polymers and registration

Duty holders will use the grouping criteria developed by ECHA, as well as the public

¹ PRR-identification criteria", 8th Meeting of REACH and CLP Competent Authorities Sub-Group on Polymers

² The Commission will still assess if Articles 118 and 119 in their current wording sufficiently cover the needs for polymers.

information from the notifications, to group polymers for registration, identify and collect the information to be submitted in the registration and to form joint submissions.

Companies will register the polymers assessed as PRR either on their own, or in groups of polymers. When grouping polymers for registration, companies must ensure to meet the given grouping criteria, and document this in the registration dossier.

Registration of polymers is foreseen to follow the existing provisions of REACH, where one (group of) polymer(s) corresponds to one registration and where a lead registrant is appointed to submit the information on the substance properties and classification on behalf of the co-registrants in the joint submission.

Upon receiving a registration dossier, ECHA will perform the completeness check and issue a registration number for the (group of) polymer(s). The completeness check may include a verification of that the criteria for grouping have been documented in the dossier but will not contain an assessment of the validity of the group.

Evaluation

ECHA will examine all testing proposals submitted in the registrations. It will perform compliance checks on registrations following the parameters that will be established for compliance check under the REACH revision. As part of the evaluation work, ECHA will carry out assessments of polymer groups, to be able to reasonably establish whether proposed studies are conducted on relevant test materials, and to be able to issue decisions to carry out new studies. To this end, the grouping is first checked against the chemical / phys-chem criteria and subsequently, an assessment will be made whether the hazard data (to be generated) covers the full extent of the polymer group. ECHA may need to conduct targeted Annex VI compliance checks to check the polymer grouping based on the available information, before proceeding to assess the (proposal to generate) Annex VII-X information.

A polymer group can nevertheless only be confirmed as valid once compliant information has been generated for all the applicable requirements.

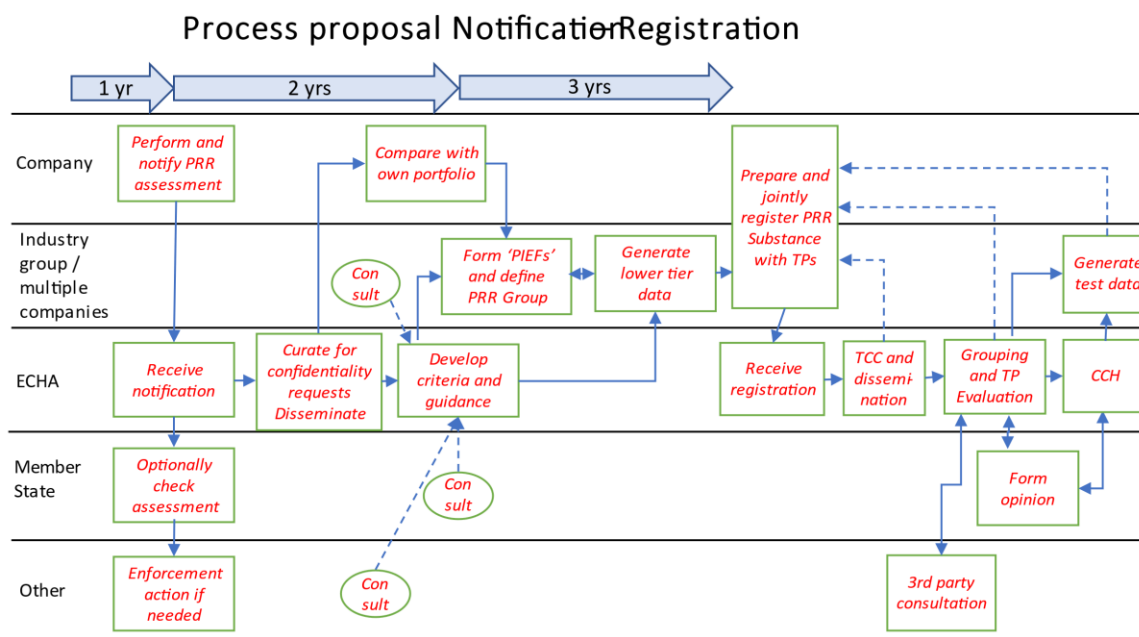


Figure 1. Proposal for registration of polymers.

Annex 1: This table provides an indicative overview of the type of information foreseen to be requested in the notification of a polymer assessed as a PRR. The last column indicates if the information is considered standard Annex VI information; information resulting from the PRR assessment; or additional information.

Name and identifiers			Source
	Chemical name(s)	IUPAC, CAS, EC, other names	Annex VI (2)
	Numerical identifier(s)	CAS, EC	Annex VI (2)
	Weight average molecular weight	Range	Annex VI (2)
	Number average molecular weight	Range	PRR
	Polydispersity index		
	Manufacturing process description	Starting materials and their ratios, polymerisation type, process conditions, purification steps	Annex VI (3)
Chemical composition of polymeric part			
	Monomer(s)	Identity and % (typical, range), Reference to registered monomers	Annex VI (2)
	Other reactant(s)	Identity and % (typical, range)	Annex VI (2)
Chemical composition of non-polymeric part			
	Constituent(s)	Identity and % (typical, range)	Annex VI (2)
	Additive(s)	Identity and % (typical, range)	Annex VI (2)
	Impurities	Identity	Annex VI (2)
	Oligomer and residual monomer content	Identity and % (typical, range)	PRR
Structural information			
	Polymer backbone	Identity, structure (block, graft, etc.), tacticity	Annex VI (2)
	Branching/Crosslinking	Identity	
	Reactive functional groups	Identity and FGEW, combined FGEW	PRR
	Fluorination	Identity, location	PRR
	Structural identifiers	Repeating unit structure, SMILES, etc., if available	Annex VI (2)
PRR assessment criteria			
	PRR assessment outcome	PRR; non-PRR; precursor	PRR
	Foreseen degradation products	Identity, classified y/n	PRR
	Control conditions for precursors		PRR
Physico-chemical characterisers			
	Log Kow		
	Physical state		

	Solubility		
	Viscosity		
	Ionicity	Ionic nature, FGEW	PRR
	Surface activity		PRR
Tonnage band			
Any available information on physico-chemical, environmental fate, bio-availability and eco-toxicological properties can be provided as part of the notification			