



EUROPEAN COMMISSION  
ENVIRONMENT DIRECTORATE-GENERAL  
Directorate B – Circular Economy & Green Growth  
Sustainable Chemicals

INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs  
DIRECTORATE-GENERAL  
Directorate D – Chemicals and Consumer Industries  
REACH  
Chemicals and Plastics Industries

Brussels, 08/12/2020  
CASG-Polymers/04/2020

## BACKGROUND DOCUMENT

for the CASG-polymers meeting 16 Dec 2020  
14:00 – 17:30

The following pages are submitted for the discussion under agenda point 3:  
Identification of Polymers Requiring Registration (PRR).

The proposed flowchart is a modification of the figure 3.2. in the Wood & PFA report on polymers. The modifications were made on the basis of feedback submitted by members of the CASG-polymers and based on discussion among the Commission services and ECHA.

It is a proposal for discussion that is not perfect yet and where some aspects of the individual criteria are not yet fully defined, but which can hopefully form the basis for a fruitful discussion.

# Identification of PRRs

## Considerations

- **CASG polymers to discuss on meaning of the PRR-criteria. The Wood report proposed this:**

*“PRR criteria are intended to provide a **pragmatic approach for identifying polymers that could possess properties that may present hazards to human health or the environment.** The criteria are developed taking into account existing experience and the available evidence on properties or features of polymers that are associated with **potential hazards to human health or the environment.** The **criteria are necessarily generalised** and if a polymer meets one or more of these criteria, it does not necessarily follow that the polymer will possess hazardous properties, but rather that the polymer should be considered as a candidate for subsequent registration whereby information on the actual hazards presented by the polymer are provided, documented and, if necessary, are assessed in more detail.”*

- **How to consider exposure:**

The views of the CASG-polymer members differ greatly as to how and when in the process exposure should be taken into account.

**Option 1** could be not to use exposure-information in the decision making if a polymer is a PRR (except for the exception of precursors shown in Fig 3.2.), but to take exposure-based considerations into account later as waiving options for certain registration requirements. This would be in line with how exposure is considered for non-polymeric substances under REACH. The flowchart in figure 3.2. is built with this option in mind.

**Option 2** could be to consider exposure already within the PRR-flowchart, i.e. in the decision making whether a polymer should be a PRR. This would bring the question what risk a certain polymer might represent forward in the discussion and make it a deciding factor prior to registration.

## **Different options for certain elements of Figure 3.2:**

- **Notification of data / assessments to ECHA (this relates also to point 4 of the agenda)**

**Option 1** (as proposed in figure 3.2 now, all green boxes) would entail that registrants who assess their polymer is not a PRR, would still notify substance ID information and documentation how this conclusion was reached to ECHA.

**Option 2** could entail that registrants keep such documentation on file in-house but must keep it available for inspection by MS enforcement authorities.

- **Polymer degradation**

**Option 1** could be to define this criterion such that only polymers that could give rise to the two substances of high concern PFAS and PFAC would become PRR.

**Option 2** could be to define this criterion such that all polymers that could give rise to a substance of concern (either SVHC or of concern based on PBT properties, or other severe hazard)

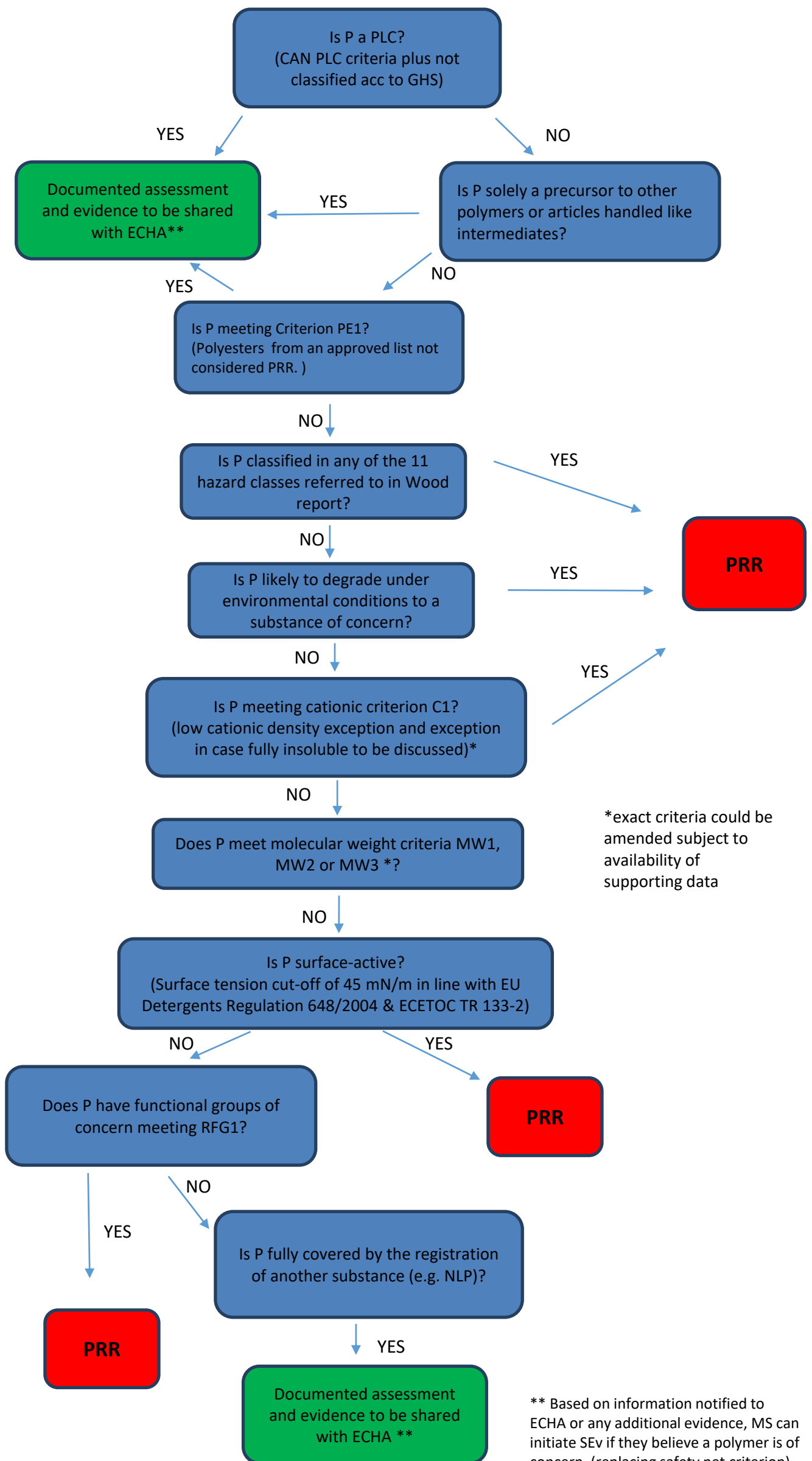
- **Possibility for MS to evaluate any polymer under Substance Evaluation (SEv)**

This refers to the textbox in figure 3.2 explaining the two \*\*. The proposal is an attempt to replace the safety net criterion mentioned in the report with another tool that allows MS to investigate certain polymers in more detail on the basis of a concern. The process envisaged would be similar to SEv for other substances today, i.e. a MS submits available information that raised a concern, other MS agree, evaluating MS can request information specific to address the concern.

**Option 1** could be to open this possibility for any polymer, not only but including those that were registered as PRR. The flowchart currently reflects Option 1.

**Option 2** could be to open this possibility only to polymers that were identified as PRR and registered. This would be more in line with how SEv functions for other chemicals today, but would not allow to assess polymers that were not identified for registration based on the PRR criteria.

**New Figure 3.2: PRR Flow chart proposal**



## Reasoning

<p>Is P a PLC? (CAN PLC criteria, plus not classified according to GHS)</p>	<p>Polymers that are PLC in other jurisdictions should not be PRR. CAN PLC criteria can be the basis, but any polymer carrying a classification should also be evaluated through the flowchart. Australia excludes polymers with a GHS-classification from being PLC.</p>
<p>Is P solely a precursor to other polymers or articles handled like intermediates?</p>	<p>Exclusion of polymeric precursors assumes that exposure is adequately controlled within industrial settings. How that is done will be notified to ECHA. The precursors can only be exempt if turned into other polymers or articles within a closed system/ like intermediates under REACH.</p>
<p>Documented assessment and evidence to be shared with ECHA**</p>	<p>If a manufacturer's assessment concludes the polymer is not meeting PRR criteria, he should notify the documented assessment to ECHA. Based on this information notified to ECHA or any additional evidence, MS can initiate Substance Evaluation if they believe a polymer is of concern. (replacing safety net criterion). Note that also in CAN, a manufacturer/importer of a PLC must submit a notification. ECHA would need to provide an IT-tool to store the information and make it available on request.</p>
<p>Is P meeting Criterion PE1? (Polyesters from an approved list not considered PRR. )</p>	<p>PE1 criterion from Wood report. Polyesters from an approved list do not need to be PRR. List can be reviewed still.</p>
<p>Is P classified in any of the 11 hazard classes referred to in Wood report?</p>	<p>If a polymer is classified in one of the following hazard classes, it should be a PRR. (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); (Ozone).</p>
<p>Is P likely to degrade under environmental conditions to a substance of concern?</p>	<p>Option 1: Polymers that can be suspected to release PFAS or PFAC should be PRR. Based on US-EPA and DK-EPA, these are mainly certain perfluorinated and side-chain fluorinated polymers. Option 2: Polymers that can be suspected to release substances of concern (e.g. SVHCs but not limited to those) should be PRR.</p>
<p>Is P meeting cationic criterion C1? (low cationic density exception and exception in case fully insoluble to be discussed)*</p>	<p>C1 is the criterion from the Wood report. Fully insoluble cationic polymers could be exempt, based on analytical proof. Low cationic density exception perhaps possible as well, to be discussed.</p>
<p>Does P meet molecular weight criteria MW1, MW2 or MW3? (cut-offs to be re-discussed)*</p>	<p>Criteria MW1 – 3 are from Wood report. Exact cut-offs could still be amended subject to availability of supporting data.</p>
<p>Is P surface-active? (Surface tension cut-off of 45 mN/m as in EU Detergents Regulation 648/2004 &amp; ECETOC TR 133-2)</p>	<p>Surface – activity is accepted to be assessed based on cut-off in the Detergents Regulation, and is also accepted to replace the specific criteria for anionics, amphoteric and nonionics.</p>
<p>Does P have functional groups of concern meeting RFG1?</p>	<p>RFG1 is the criterion of the Wood report.</p>
<p>Is P covered by the registration of another substance (e.g. NLP)?</p>	<p>Where the polymer is directly related to already registered structures of lower MW, its risk can be characterised by the information on the low MW version, and separate registration is not valuable. Also here, assessment and evidence to be notified with ECHA, so that information can be checked in case of concern.</p>