

28 January 2021

Summary of the EEB's and ChemSec's positions with regard to the three documents discussed during the 2nd meeting of the CARACAL's CASG-polymers subgroup on December 16, 2020.

1. Concerning the document "Draft Minutes. 1st Meeting of REACH and CLP Competent Authorities Sub-Group on Polymers. 11 September 2020 10:00-17:00."

We remind that we have submitted a list of our comments and editing requests in a separate document prior to the 2nd CASG-polymers meeting. We kindly ask to take those into consideration.

2. Concerning the document "The European Commission's plans on unintentionally released microplastics. DG ENV Dec 2020."

We appreciate the Commission's effort to summarize its plans on unintentionally released microplastics. Nonetheless, we maintain our position stating that (i) the initiatives realized to date are not yet sufficient to tackle this important problem in its entirety, (ii) the ongoing discussion of the future process for polymer registration under REACH should include the consideration of secondary microplastics, and (iii) generation of microplastics as a result of tear/wear/aging processes is an inherent hazardous property of products made of polymeric substances and therefore this property and its consequences for human and environmental exposure and risks should be taken into consideration both when deciding which polymers should be registered and when laying down the data requirements applicable to pre-registration and full registration submissions.

We observe that the presented document on the Commission's microplastics plans focuses in large part on summarizing the Commission's work on intentionally produced microplastics, including plastic pellets – in other words, primary microplastics – but much less on secondary microplastics and their generation from larger plastic objects during the use and end-of-life phases. Furthermore, even those initiatives intended to partially tackle the secondary microplastics problem are hardly sufficient and/or have not yet been fully implemented to date.

The latter is particularly true with regard to the so-called "single-use plastics directive," i.e., Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment, to which the quotation from Ursula von der Leyen's political guidelines 2019-2024 (see page 4 of the "microplastics plans" document) probably refers (i.e., the part stating that "European legislation already applies to the ten most found plastic items on European Beaches"). We remind that the preamble (8) of this Directive states that "Microplastics do not fall directly within the scope of this Directive, yet they contribute to marine litter and the Union should therefore adopt a comprehensive approach to that problem." We believe that "a comprehensive approach" should necessarily include the consideration of secondary microplastics issue when laying down the criteria for identification of polymers requiring registration. At a very minimum, basic microplastics-relevant information should be

requested during the mandatory pre-registration procedure for *all* polymers produced and/or imported in the EU, and these data should cover at least the identity and physico-chemical properties of a polymer, particularly with regard to its propensity to shed micro- and nanoplastics during the use or disposal phases, as well as its production volumes and downstream uses, again viewed in the light of estimating the proneness of the polymer and the products made thereof to generate microplastics releases and thus contribute to microplastics exposure burdens in the environment.

Comprehensive baseline information systematically collected in this way will be particularly instrumental in supporting the Commission's initiatives outlined on page 5 of the "microplastics plans" document, specifically the last three, i.e., "Developing labeling, standardization, certification and regulatory measures on unintentional release of microplastics"; "Further developing and harmonizing methods for measuring"; and "Closing the gaps on scientific knowledge related to the risk and occurrence of microplastics in the environment, drinking water and foods." We observe that such information is largely missing at present. This makes not only its systematic collection but also the subsequent open sharing of collected information all the more important.

3. Concerning the "Background Document for the CASG-polymers meeting 16 Dec 2020 14:00-17:30."

We understand that the presented document represents only "a proposal for discussion that is not finalized yet and where some aspects of the individual criteria are not yet fully defined." For the sake of clarity, in the following we summarize and complement our position as said during the meeting.

Regarding "CASG polymers to discuss on meaning of the PRR criteria" (p. 2). We believe that polymer registration should follow the same principles than other chemicals under REACH and aim to register all polymers through a stepwise approach. If the proposal to only register the identified PRRs in order to ease the burden on industry goes ahead, then it is important to ensure that the formulated PRR criteria will not limit the scope of the polymers covered excessively. The criteria must be broad enough to cover all polymers which could present potential hazards in order to flag them as candidates for subsequent registration. Whether the polymer presents this hazard, as well as the extent of the resulting risks, should in general be only taken into consideration at a later stage following the registration. However, it can be discussed whether differential data requirements for individual full registration submissions could be defined depending, e.g., on production volumes and exposure considerations etc.

Regarding "How to consider exposure" (p. 2). We observe that the two options outlined in the Commission's document need to be better defined, because different meeting participants appeared to adhere to drastically differing interpretations of the same text. We support Option 2 in a sense of including the exposure volumes as one PRR criterion, i.e., polymers which have very high production volumes and/or widespread downstream uses, likely resulting in high exposure (including microplastics exposure) of humans and the environment, should be identified as PRRs. However, we are decisively against formulating this option as an opportunity to avoid a polymer's consideration against PRR criteria on the premise of "no exposure" or something similar. From this point of view, we would be more for the Option 1, where exposure is not considered for waiving registration requirements but where flexible data requirements could be established for registered polymers depending, e.g., on production tonnages.

Regarding "Notification of data/assessments to ECHA" (p. 2). We support Option 1 with notification of data and assessments to ECHA for all polymers (i.e., both green boxes in figure 3.2), and we further call for extending the notification conditions towards making the

non-confidential data publicly available through ECHA website, as is currently done for non-polymeric substances.

Regarding “Polymer degradation” (p. 2). We support Option 2 and call for both an explicit and broad definition of “substances of concern,” which should cover not only substances included on the REACH Candidate list or substances meeting the definition of being substances of very high concern (SVHCs). The definition “substances of concern” should be considerably broader and include also other recognized hazardous substance properties. We further urge taking secondary microplastics into consideration as well, since microplastics should in essence be seen as products of polymer degradation, which can be associated with environmental and human health concerns.

Regarding “Possibility for MS to evaluate any polymer under Substance Evaluation (SEv)” (p. 2). We support Option 1. Given the much lower availability of publicly accessible data on polymers’ chemistry and hazards, and hence the resulting lack of experience with identifying hazardous polymers of concern, it might occur that not all polymers of concern will be “caught” based on the criteria which will be formulated in the first iteration. Therefore, Member States should retain the opportunity to evaluate any polymer, not only the ones identified as PRRs, shall such necessity arise in the future based on, e.g., new scientific knowledge or altered use considerations, etc.

Regarding “New Figure 3.2: PRR Flow chart proposal” (p. 3):

A general comment concerns the need to better explain the statements in the boxes, since in several cases the meetings’ participants put forward different interpretations of the same short text parts.

Blue box “Is P a PLC?” PLC criteria should be clearly defined and presented with corresponding considerations and/or justifications based on scientific knowledge, transparently presented industry data, or experience in other legislations worldwide. It is not enough to simply say that Canadian criteria will be taken. Each criterion should be listed separately and the resulting list should potentially undergo group discussion and adoption procedure as well. Further, it should be transparently justified, why the choice fell on “Canadian” criteria and not, for example, the “Korean” ones, or not the criteria outlined in the 2015 study by the Commission itself? These considerations require explicit listing and justification along with the proposed final list of PLC criteria. Further, it should also be clarified which sources of GHS classifications should be considered and whether an identification of a GHS classification referring to the “11 types identified in the Wood report” would not already identify the polymer as a PRR, making other steps obsolete.

Green box “Documented assessment and evidence to be shared with ECHA.” As already stated above, we support this procedure and further call for (i) obligatory inclusion of data on production volumes and downstream uses as well as (ii) provision of public access to submitted non-confidential information. Confidentiality claims should rely on verifiable justification that the disclosure may cause a significant harm to a legitimate interest, and be systematically assessed by ECHA, considering that transparency must be the rule and confidentiality the exception to interpret strictly. The same considerations also apply to the second green box shown at the bottom of this figure.

Blue box “Is P solely a precursor to other polymers or articles handled like intermediates?” We observe that this step seems to partially bring in the “exposure consideration” option discussed above, where the notion of “no exposure” was proposed to be used as a waiver to avoid polymer registration. Before a conclusive discussion can be carried out on this aspect, the terms “precursor” and “intermediate” need to be clearly defined and agreed on, and the situations appropriate for “waiving” need a much more explicit definition as well. The rationale of the exemption should be a reliable control inherent to the process that guarantees (as much as possible) no emissions/exposure. Thus, in situations where polymer

is a true intermediate, never appearing in the final polymer and handled only in closed systems during the production process, such “waiving” could be appropriate. In situations where, e.g., a pre-polymer leaves the production site, is being transported and delivered to downstream users to be used in preparation of their articles, such “waiving” would be inappropriate and such polymer should be evaluated against all PRR criteria without exemptions.

Blue box “Is P meeting Criterion PE1?” This step proposes a general exemption for “polyesters from an approved list.” We disagree with this proposal to exempt polyesters due to the incompleteness and general lack of transparency with regard to scientific justification behind this proposal, as well as the compilation of the “approved list.” We note that polyesters have drastically differing properties with regard to molecular weight distribution as well as oligomer contents and hazardous properties of these oligomers. In particular for the cyclic oligomers of some polyesters, their toxicity is not yet sufficiently characterized to allow making such generalizing exemptions. Furthermore, many polyester-based products are known to generate high amounts of secondary microplastics, which should be taken into consideration as well.

Blue box “Is P classified in any of the 11 hazard classes referred to in Wood report?” We support this criterion but observe that it needs clarification with regard to whether only the European classifications or also the worldwide classifications should be considered, as this could help expand the rather limited state of knowledge and classifications existing for polymers in Europe. Furthermore, we note that the currently formulated hazard classes may not be sufficient to capture all potential hazards of polymers (e.g., those not requiring uptake or high levels of systemic exposures). However, we agree that this discussion may go beyond the reach of the CASG-polymers subgroup for the moment. Nonetheless, we suggest that this criterion should explicitly acknowledge the possibility to include additional types of hazards shall this appear necessary as the scientific understanding develops further.

Blue box “Is P likely to degrade under environmental conditions to a substance of concern?” We support this criterion and particularly the related Option 2, as described above.

Blue box “Is P meeting cationic criterion C1?” We support this criterion and underline that the exception conditions require further discussion as already noted in the document itself. We further urge including a similar criterion for anionic polymers as well, as was originally proposed in the Wood report. We point out that the group of anionic polymers is not limited to only the substances acting and used as surfactants (and therefore presumably covered with the subsequent criterion about surface activity), but also includes other polymer types which are used in other applications and can exhibit other toxic properties. In this regard, the ECETOC’s TR133-1 report on polymers indeed states that “it might be hypothesized that that surface activity is a more precise alert than presence of anionic groups,” but also acknowledges the remaining uncertainty “where further analyses of datasets will be helpful.”

Blue box “Does P meet molecular weight criteria MW1, MW2 or MW3?” We support this criterion and note that it should also cover considerations with regard to oligomer contents. The exact thresholds for MW values and oligomer content levels require a separate discussion and justification, as we have already commented in our earlier feedback to the proposals outlined in the Wood report.

Blue box “Is P surface-active?” We support this criterion but emphasize that additional discussion regarding the chosen threshold of 45 mN/m reduction in surface tension may be necessary. The 45 mN/m reduction in surface tension has been previously set as a threshold to identify surfactants in general, particularly in the context of the EU Detergents Regulation. However, whether the unchanged threshold can be directly applied to the field of polymers requires further consideration and potentially empirical investigation. In this regard, the

ECETOC's TR133-1 report on polymers also acknowledges that "[r]esearch work is merited to evaluate if this regulatory threshold would qualify as a criterion to distinguish potentially eye / skin irritating surfactant polymers from PLC."

Blue box "Does P have functional groups of concern meeting RFG1?" In general, we support this criterion but refer to further specific comments for this criterion, which we have already provided in our feedback to the detailed proposals regarding applicable MW threshold groups and RFG severity assignments, as outlined in the Wood report.

Is P fully covered by the registration of another substance (e.g. NLP)? We support this criterion but emphasize that the specific definitions and exemption cases and procedures should be explicitly and transparently defined. E.g., what exactly is meant with being "directly related" in this case? It should also be considered whether this particular criterion should be moved higher up in the proposed decision tree.

Replacement of the safety net criterion. It is not clear what the justification for removal of the safety net criterion was and whether this would be against the REACH principles by placing a much higher level of responsibility and burden on the Member States instead of on the producer, as would have been required by REACH.

Omitted criteria. Several other criteria which are currently not included in the proposed PRR identification scheme should either be included or a detailed and transparent justification for their exclusion should be provided and openly discussed with the whole group. Such criteria include, for example, criterion for amphoteric polymers; criteria for impurities and for stability-preserving additives present in polymers; criterion for water-absorbing polymers; criterion for elemental limitations; criterion for nanopolymers; criterion concerning generation of secondary micro- and nanoplastics; and criteria for high production tonnage and widespread use.