CHEMSEC AND EUROPEAN ENVIRONMENTAL BUREAU COMMENTS TO WOOD AND PFA REPORT ON POLYMER REGISTRATION

We thank the consultancies Wood and PFA for the outstanding work performed to deliver their 2020 report for the European Commission titled "Scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment" (thereafter referred to as Wood&PFA report). This report documents scientific evidence, acknowledges remaining uncertainties, and outlines the assumptions and considerations involved in developing the criteria for the identification of polymers requiring registration (PRRs) under REACH. In their report, Wood and PFA state the following:

> *"Polymers are on the market in very high quantities, and very little is known about many of them, based on literature surveys conducted to date. The experience of REACH to date, in which much new information came out from the manufacturers' own systems, could be repeated for PRRs, which would be* ***a very significant gain for human and environmental protection****."*

We strongly agree with this statement. The work on polymers registration under REACH is very important and cannot wait any longer. We emphasize that **the ultimate measure for judging the appropriateness of the adopted polymer registration process and criteria should be not to provide for the least burden on industry but to ensure a high level of protection of human health and the environment**. Therefore, while appreciating the consultancies' work, we nonetheless would like to highlight several areas in the current report where we question some of the assumptions made, object exclusion or modification of some of the proposed criteria for PRR identification, suggest inclusion of additional criteria, and propose initiation of a mandatory pre-registration (initial notification) process to collect a defined minimal set of data for all polymers in the EU.

During the **pre-registration phase**, which should start as soon as possible, the European Chemicals Agency (ECHA) should receive **a minimal set of data for *all* polymers manufactured or imported into the EU**, i.e., including not only the suspected PRRs but also the presumed so-called "polymers of low concern" (PLCs) as well as everything "in-between." After attending to only the strictly indispensable confidentiality claims, the submitted data should be immediately made publicly accessible to enable interrogation by authorities, academics and NGOs. The scope of submitted data should include all information necessary to make a decision on whether a polymer is a PRR. Since the industry will need to compile these data anyway in order to carry out their own assessments, only little additional costs can be expected to arise from transferring this information to ECHA, while the benefits to be gained are immense. First, these pre-registration data will provide the much-needed ***overview*** on the numbers, types, production volumes, applications, and characteristics of polymers in the EU. This will provide necessary ***oversight*** and ensure ***transparency***, thus facilitating ***enforcement*** and strengthening ***public trust*** in polymer safety assessments. These data will also allow ***refining the cost-benefit analysis***, currently limited by many uncertainties, and will facilitate further ***development of***

hazard assessment and grouping approaches, thus providing for more efficient and less costly full registration activities. A mandatory pre-registration requirement for all polymers goes in line with processes followed for non-polymeric substances and is in general long overdue in order to comply with the ***"no data no market"*** principle of REACH.

With regard to the underlying assumptions used when developing PRR registration criteria, we regret to see that the presented analysis does not address the issue of environmental pollution by macroplastics and secondary **microplastics and nanoplastics generated from polymers** during the production, use, and end-of-life phases. Both the ***persistence*** as well as ***propensity to generate micro/nanoplastics*** are ***inherent hazardous properties*** of many polymers. Taking into account the widespread exposure to micro/nanoplastics and continuously accumulating scientific evidence on the resulting adverse effects on human health and the environment, it becomes imperative that the proposed process for polymer registration under REACH properly addresses this issue by considering the persistence and micro/nanoplastics generation hazards within the risk assessment scheme and subsequent risk management goals. Consideration of environmental pollution issues also provides a strong support to including a **PRR identification criterion focused on extremely high production volumes** in association with widespread downstream uses prone to micro/nanoplastics generations and/or end-of-life mismanagement. Requirements for test data necessary to estimate exposures as well as to characterize hazards of secondary micro/nanoparticles should also be included as part of a full registration package where necessary.

We further **object to reformulation or outright exclusion of some of the criteria for identification of PRRs** as proposed in the Wood&PFA report, because in most cases none or very little scientific evidence has been presented as a justification for these wide-reaching decisions. This concerns, for example, the chosen focus on systemic bioavailability only, while disregarding the potential local effects and interactions with microbiota, and the resulting molecular weight (MW) cut-off thresholds; the unjustified increase in the % threshold for low molecular weight oligomer content; derogation for polymers that could become cationic or amphoteric in the environment; a lack of criteria for polymers with non-carbon backbones; the exclusion of criteria dealing with stability-preserving additives or impurities, although these form an inherent part of a polymer according to REACH definition; the unjustified exception for polyesters; and the exclusion of criteria addressing large production volumes, exposure potential, and degradability considerations. Substituting the now-excluded criteria by a vaguely formulated "safety net criterion" cannot be expected to provide sufficient level of protection of public health and the environment, therefore exclusion of those criteria is not justified and should be reconsidered.

The above-mentioned issues should form the basis for further discussion between the stakeholders. Below we provide a more detailed account of NGO position and arguments, presented as responses to the agenda items scheduled to be discussed during the 1st Meeting of REACH and CLP Competent Authorities Sub-Group on Polymers on September 11, 2020.

1 st Meeting of REACH and CLP Competent Authorities Sub-Group on Polymers on September 11, 2020.

EEB and CHEMSEC responses to the agenda items questions.

Agenda item 2. Identification of Polymers Requiring Registration (PRRs)

a) Are the suggested criteria for identifying PRRs appropriate?

Response:

Some of the criteria are appropriate, while others require revision or should be supported by publicly available scientific evidence which is currently lacking. Yet several more criteria which are currently excluded on the basis of scientifically unconvincing reasoning should be included again, or their exclusion should be justified with solid evidence accessible to public scrutiny. A detailed account of our comments and suggestions for modifying criteria for identifying PRRs presented in the Wood&PFA document is provided below.

Criteria for hazard classifications under the CLP regulation

We support the proposed criteria but point out that the exclusion of Eye Irritation 2 and Skin Irritation 2 classifications does not appear to be justified by sufficiently broad scientific evidence and therefore needs to be reconsidered. We further emphasize that the Wood&PFA report stresses that "*the classification here should relate to the polymer itself (i.e. those constituents that fall within the REACH definition of a polymer). Specifically excluded are classifications that result from the presence of monomers or additives other than those necessary to preserve the stability of the polymer*" (p. 67). Thus, since both the stability-preserving additives and impurities do fall within the REACH definition of a polymer, the criteria on hazard classifications should apply to these substances as well. Based on this, we disagree with the later-appearing proposal to exclude the stability-preserving additives and impurities from consideration (see further comments in a respective subsection below).

Criteria for cationic polymers

We support the criterion identifying polymers that are cationic as PRRs, and we object the proposal to not consider polymers that could potentially become cationic in the environment as PRRs. In support of their decision, Wood&PFA cited "experience from regulators [which] suggests that for such polymers protonation generally occurs only on a few sites and they rarely become highly protonated" as well as the "general agreement at the workshop that a criterion based on the potential to become cationic was not needed." We consider the "experience from regulators" to be inconclusive (besides the fact that it is not available for public scrutiny). The "general agreement" reached at a workshop dominated by industry could be potentially biased. Therefore, exclusion of this criterion does not appear to be sufficiently justified, and it should be included again, i.e., polymers that could potentially become cationic in the environment should be considered PRRs. The registrants should then provide data necessary to understand, e.g., the conditions at which protonation could occur as well as the degree of potential protonation, and these data should then be used as a basis for risk assessment of polymers in question. The proposed exception for polymers with low cationic density is acceptable provided the combined equivalent weight threshold is not set lower than 5,000 Da.

With regard to human health concerns from cationic polymers, we highlight that not only the inhalation route and lung toxicity but also the ingestion route and resulting effects on gut microbiota may need to be considered.

Criteria for anionic polymers

We support the criteria identifying as PRRs polymers that are anionic or are anticipated to become anionic in a natural aquatic environment. The proposed exception for polymers with low anionic density is acceptable provided the combined equivalent weight threshold is not set lower than 5,000 Da.

Criteria for amphoteric polymers

We support the criterion identifying polymers that are amphoteric as PRRs. Similar to the situation with cationic polymers, we disagree with the decision to not consider polymers that could potentially become amphoteric in the environment as PRRs. Given the general scarcity of data on polymers, "experience from a regulator" cannot be used as a sole basis for making wide-reaching decisions. The Wood&PFA report itself acknowledges that there are "currently insufficient data available to investigate" this aspect. Therefore, polymers which could potentially become amphoteric in the environment should be identified as PRRs to ensure subsequent generation of data necessary for risk assessment. The proposed exception for polymers with low cationic and anionic density is acceptable provided the combined equivalent weight thresholds are not set lower than 5,000 Da.

Criterion for nonionic polymers with surface-active properties.

We support the criterion identifying polymers that are nonionic with surface-active properties as PRRs.

Criteria for low molecular weight oligomers

We fully support the inclusion of PRR identification criteria based on the content of low MW oligomers. However, we emphasize that both the MW cut-offs characterizing the low MW constituents and the % cut-off values for their content that shall trigger PRR identification require further discussion and possibly revision.

First, the widely used MW cut-offs of 500 Da and 1000 Da are based on partially outdated scientific evidence and may require future reconsideration in light of (i) potentially increased intestinal permeability occurring as a result of chemical exposure to permeation enhancers, as a result of certain diseases, or in specific population groups such as infants and elderly; (ii) possibility of local effects occurring irrespective of systemic uptake, including local inflammation, allergic responses, and effects on microbiota.

Second, the criteria text should include specification for per- and polyfluoroalkyl substances (PFAS) covering fluoropolymers, where, even based on the pure systemic uptake assumptions, the upper cut-off value of 1,500 Da could be more appropriate, because the molecular volume of C-F bonds is smaller than that of C-H bonds, leading to lower molecular volume of the molecules with the same molecular weight. Similarly, by analogy, it could be appropriate to consider all fluoropolymers with average molecular weight <1500 Da to be PRRs. The MW-based divisions into Type 1, Type 2 and Type 3 for fluoropolymers should also be revised accordingly.

Third, ***the proposed % cut-off values for the content of low MW constituents content are too high and should be lowered***. The Wood&PFA report proposes that both the Type 2 (1000 <MW_n<10,000 Da) and Type 3 (>10,000 Da) polymers are considered as PRRs if they contain ">10% oligomer content of molecular weight below 500 Da or >25% oligomer content of molecular weight below 1000 Da." These thresholds are outrageously high – consider only that, upon reaching these limits, one quarter of a Type 3 polymer could essentially be considered as a Type 1 polymer! Most polymeric products with such high contents of low MW oligomers would not maintain their structural integrity due to high migration and deterioration of the material.

The criteria proposed by Wood&PFA differ from those formulated in the COM (2015) study, where lower cut-offs (>2% and >5% for molecular weights below 500 Da and 1,000 Da, respectively) were proposed for the Type 3 polymers. Wood & PFA explained their decision to adopt the same, high % cut-offs for both Type 2 and Type 3 polymers with reasoning that the differing cut-offs for the two MW ranges are "*difficult to reconcile scientifically as there is no reason to suppose that the low molecular weight oligomers present in polymers with MW_n >10,000 Da would be any more hazardous, and thus warrant a lower cut-off content, than the low molecular oligomers present in polymers with MW_n<10,000 Da.*" We agree with the observation that there seems to be no clear reason to adopt different % thresholds for Type 2 and Type 3 polymers, but we strongly disagree with the arbitrary decision to adopt higher instead of lower values for % thresholds.

Based on the considerations above, we suggest that the % thresholds for identifying both Type 2 and Type 3 polymers as PRRs should be >2% for oligomer content of MW below 500 Da and/or >5% for oligomer content of MW below 1,000 Da. However, at this point it is also worth noting that in Japan an even stricter criterion, i.e., a single cut-off of 1% for oligomers with molecular weights below 1,000 Da is used for all polymers. We also stress that mixtures containing hazardous substances of very high concern (SVHCs) are identified as hazardous if SVHC content is above 0.1%. Therefore, once more data and experience with hazard assessment of oligomers and other low MW constituents, including non-intentionally added substances (NIAS) present in polymers, will become available, even a further reduction of the 2%/5% thresholds may need to be considered.

Criteria for reactive functional groups

We agree with the criterion to identify the Type 2 (1000<MWn<10,000 Da) polymers as PRRs if they contain reactive functional groups in the high-concern and/or moderate-concern category.

We request that the decision to consider the Type 3 (>10,000 Da) polymers as PLCs "regardless of the types of reactive functional groups present" be supported by publicly presented, strong scientific evidence demonstrating the general insignificance of reactive functional groups for determining the hazard of polymers with MW >10,000 Da. So far, such comprehensive evidence seems to be generally lacking and therefore this exception is not justified.

For the sake of clarity and completeness, we suggest to consider listing in the high-concern group those types of functional groups which were newly identified to be associated with structural alerts for toxicity, as found by the Wood&PFA analysis shown in Annex G. On the other hand, profiling with the OECD QSAR toolbox alone does not constitute a sufficient proof of the lack of toxicity for amides, non-pendant esters, and ketones functional groups. Therefore, before their potential addition to low-concern group is further considered, we suggest that an additional evidence analysis (e.g., literature review) should be performed to ensure the absence of other toxicities which might have been missed or underrepresented within the OECD QSAR toolbox.

Criteria for impurities and for stability-preserving additives present in polymers

In the section dealing with definitions, the Wood&PFA report explains that the substance definition in REACH Article 3(1) states that additives used in the manufacturing process which are necessary for preserving the stability of the polymer should be considered as part of the substance and as a consequence do not have to be registered separately. A similar treatment is given to impurities, which are considered to be part of the substance and do not have to be registered separately. In contrast, additives which are not necessary for preserving the stability of the polymer are not considered to be an inherent part of the polymer. Instead, polymeric material containing such substances "should be considered as a mixture or an article," and a "normal registration requirements" would apply for such substances. Similarly, unreacted monomers are considered to be outside of the polymer registration scope, because registration of monomers is already covered under REACH article 6(3) and "both the reacted monomers and unreacted monomer should be covered in the same registration dossier for that monomer substance."

Thus, impurities as well as additives which are necessary to preserve the stability of the polymer are considered to be constituents of the polymer and should be considered and registered together with the polymer. Specifically with regard to the additives necessary to preserve the stability of the polymer, the Wood&PFA report further states that "it is possible that in some cases these may themselves already be registered as substances in their own right. However, that may not necessarily be the case in all circumstances." Since the true extent of already existing registrations for the stability-preserving additives is currently not known, it appears prudent to request the submission of these data during pre-registration (i.e., initial notification phase) in order to get a reliable overview. The fact that "currently there are no obligations under REACH for a manufacturer or importer of a polymer to register the quantity of additives necessary to preserve the stability of the polymer as these are considered as part of the polymer" lends further support to the necessity to ensure systematic collection of these data, which should then serve as the basis for making future decisions in this regard.

Based on the above considerations, we disagree with the Wood&PFA decision to "not specifically include[] [criteria] for identification of polymers requiring registration based on the content of additive required to stabilise the product and minor constituents." The presence of hazardous stability-preserving additives or impurities may bear a high contribution to the hazard profile of a polymer as a whole, thus justifying the establishment of appropriate criteria for its identification as a PRR. By analogy, the threshold for SVHC content in mixtures is set at 0.1%. As an example, both polyethylene (PE) and polypropylene (PP) plastics (polyolefins) require the addition of antioxidants which are necessary to prevent degradation of the polymer and are often used alone or in combination at the levels of 0.5-1%. In polyethylene terephthalate (PET) plastics, antioxidants are usually not added, but instead UV absorbers are often used for stabilisation, because the main pathways of PET degradation during use include photolysis and photo-oxidation reactions. Polyvinyl chloride also requires the presence of stabilizers to protect the polymer during the thermal processing as well as the use phase. Besides, both polyvinyl chloride and polystyrene plastics are made in the condensed phase (as opposed to polyolefins which are usually made through gas-phase processes). Reactions carried out in the condensed phase require the use of carrier solvents, surfactants and emulsifiers, etc., and residues of these polymerisation aids often remain in the resultant plastics.

Given the high production volumes of the above-discussed plastics types, the amounts of the stability-preserving additives used there, as well as of impurities present, may be far from negligible. Indeed, some of these additives have already been registered under REACH and some of them are even already recognized as SVHCs or are currently being assessed in this regard. Yet other substances may remain completely unknown unless they are revealed during the polymer pre-registration and/or registration process. Information on the use patterns of specific

substances in polymers will also be very instrumental for initiating and supporting the efforts aimed at substitution of hazardous chemicals by greener alternatives. Based on these considerations, the decision to remove the criteria for considering the impurities and additives necessary for preserving stability as part of PRR identification process is not justified. This specifically implies, for example, that, if any of the additives necessary for preservation of stability of a given polymer are classified with any of the hazard classifications listed in the criteria "Polymers classified as hazardous under the CLP Regulation," then this polymer should be flagged as a potential PRR. Testing requirements and the breadth of data requested during full registration for PRRs falling within this group may need to be adopted though, which could be subject of further discussions.

Criteria for degradable polymers and missing criterion for generation of secondary micro/nanoplastics

The Wood&PFA report proposes to not include any PRR identification criteria based on degradability, arguing that "*the fact that a polymer is itself degradable, either biologically or by other mechanisms, is itself not a parameter that would lead to a concern over the polymer.*" We disagree with this conclusion.

First, we regret to see that the degradability discussion did not mention the special group of oxo-degradable plastics. In our opinion, an oxo-degradable polymer (e.g., imported) should be immediately flagged as a PRR.

Second, we find the decision to not include degradability as a PRR identification criteria to be directly contradicting other statements made in the same Wood&PFA report. For example, on p. 65 it is stated that "*possibility of formation of degradation products that are equally or more bioavailable and/or toxic than the polymer itself during use*" represents one of the hazards which would identify a polymer as PRR. We consider that secondary microplastics and nanoplastics generated from polymers should be seen as an important type of such "degradation products" and argue that the discussion on degradation should not be limited to biodegradation but should consider the contribution of physical degradation as well, because this process leads to generation of polymer fragments which could be taken up by the organisms or interact with them in other ways, thus causing diverse adverse effects potentially leading to deterioration of health and environment. Therefore, polymers that contribute to the environmental pollution by secondary micro/nanoplastics do fall exactly within this hazard category, and there is a clear need for an additional PRR identification criterion that should deal with the polymer's propensity to generate micro/nanoplastics and consider specifics of its downstream uses with regard to potential contribution to environmental pollution with micro/nanoplastics.

In the Table 2.1 (Substances covered by the scope of the study and those which are not to be included) the Wood&PFA report states with regard to "microplastics" that "there will not be an approach specific to microplastics, i.e. no specific considerations will be developed in relation to particle size when developing the requirements for PRR. Therefore, polymers produced in microparticle size will be in the scope but microplastics generated through the breakdown in the environment of larger plastics [(i.e., secondary microplastics)] are outside of the scope of the report." However, "polymers produced in microparticle size" (i.e., intentionally produced microplastics) are already being tackled within a restriction proposal being developed by ECHA. Therefore, taking them "in the scope" here essentially means duplicating the already ongoing efforts. In contrast, generation of secondary microplastics has not yet been properly addressed by any specific legislation initiative. Since the propensity to generate micro/nanoplastics is an inherent property of many polymers, it should be considered as one of the hazards to be addressed and therefore should be handled within the polymer registration process under REACH.

Based on these considerations, we cannot comprehend the logic behind the Wood&PFA's decision to include primary but exclude secondary microplastics from the scope of their study, unless one assumes that this was done as a result of a general unwillingness to invest resources into addressing this important contemporary problem which arose as a direct consequence of polymers' production and use, or, worse, in order to "protect" the largest contributors to micro/nanoplastics pollution, i.e., polymers produced in extremely high quantities for largely single-use downstream applications. Both justifications cannot be accepted because they fail in the face of the original mission of REACH, which is to ensure high level of protection of human health and the environment. Therefore, we request that generation of micro/nanoplastics and the resulting pollution, exposure, and effects on human health and the environment do receive all due consideration when developing the process and criteria for polymer registration under REACH.

This recognition may also require a reconsideration of the concept of "polymers of low concern" being those polymers "deemed to have insignificant environmental and human health impacts" and therefore agreed to have "reduced regulatory requirements," because many PLCs may in fact bear a large contribution to micro/nanoplastics pollution of the environment. Many polymers are actually "very persistent," but the question about their bioaccumulation properties, including in the form of micro/nanoplastics, often cannot be conclusively answered due to as-of-yet unresolved analytical challenges. This, however, does not exclude the possibility that the bioaccumulation potential will be demonstrated in the future once better analytical approaches become developed and widely available. Diverse other aspects related to proper consideration of the micro/nanoplastics issue are highlighted in relevant places throughout this document.

Unjustified exclusion for polyesters

The Wood&PFA report proposes including a "specific exclusion for polyesters" which should not be identified as PRRs regardless of their MW_n or % thresholds of low MW oligomers content. This decision is put forward despite acknowledging that "the experimental justification behind these exclusions is not clear." Indeed, the COM (2015) study gives an exception for polyesters, i.e., "if the candidate polymer is a polyester from an approved list, it is considered a polymer of low concern regardless of the number average molecular weight or oligomer content." This statement is, however, rather contradictory, given that the same document suggested another criterion which excludes degradable plastics from the PLC eligibility. The original reasoning for offering a "special treatment" for polyesters was the expectation that all polyesters will eventually hydrolyse to their monomers, and if these monomers are not hazardous, then the polymer is not hazardous as well. However, the rate of polyester degradation heavily depends on the environmental conditions and many polyesters are in fact known to be very persistent in the environment. Therefore, the assumption that polyesters will *always* be quickly hydrolyzed to their (unhazardous) monomers cannot be justified. The available empirical evidence does not lend much support to this idea either: more often than not, many polyesters exhibit notorious recalcitrance, non-degradability and persistence under environmental conditions, see, e.g., the behavior of PET plastics widely dispersed in the environment as water bottles, containers, textile fragments, and micro/nanoplastics.

Given the above considerations, specific exclusion of polyesters from consideration through other PRR criteria, including the criterion dealing with micro/nanoplastics generation, does not appear to be justified.

Criterion for water-absorbing polymers

The Wood&PFA report proposed to not include any PRR identification criteria dealing with water-absorbing polymers. However, the report acknowledges the existence of unresolved "concerns over carcinogenicity for high molecular weight water-absorbing polymers." In such a situation, uncertainties should be resolved by additional studies which should then serve as a basis for a decision on including or excluding this criterion. In contrast, an arbitrary exclusion of this criterion without providing further evidence does not appear to be justified. In response to these concerns, the approach taken, for example, by the US Environmental Protection Agency (USEPA) currently is to assess "on a case-by-case basis whether water-absorbing polymers pose a risk and whether further testing is warranted." We suggest that the same approach be followed in the EU until more data become available which could resolve the remaining uncertainties. Thus, water-absorbing polymers should not be by default excluded from being PRRs, but instead should be identified as potential PRRs, followed by a case-by-case assessment to decide which kind of testing would be necessary to confirm their safety.

Criterion for elemental limitations

In contrast to the COM (2015) study, the Wood&PFA report proposes not to include any criteria based on elemental limitations when identifying PRRs. However, it does acknowledge that many types of inorganic polymers exist which have "backbones based on silicon, oxygen, phosphorus, sulfur, boron, nitrogen, germanium, and/or tin for example," and that "little information is currently available on the hazards of these types of polymers." We disagree with the argument that "the safety net criterion" will be efficient in reliably identifying hazardous polymers from this large group. Instead, we propose that information on such polymers be systematically collected during the pre-registration (initial notification) phase. The obtained overview should then serve as a basis for making future decisions in this regard.

Criterion for nanopolymers

Similarly to what has just been discussed above, we propose that the data collected during the pre-registration (initial notification) phase should include details on potential nanoforms. The obtained overview will support future approaches to handling nanopolymers which could be identified as PRRs. We also point out that a substantial scientific evidence demonstrating toxicity of nanoplastics has already been compiled in documentation supporting the ongoing restriction process for primary microplastics.

"A safety net criterion"

We welcome the introduction of the safety net criterion as the additional means to capture hazardous polymers not covered by other criteria. However, we disagree with the approach to expect that this criterion should be positioned as the sole means to deal with polymers which could be covered by other, specifically formulated, criteria which Wood&PFA for various reasons decided not to include, as discussed above. We maintain that, if a specific criterion can be formulated, then it should be included as such, rather than relying on the broad "safety net" approach to cover the multiple instances possible.

Criteria for high production tonnage and widespread use

We propose that there should be an additional criterion for polymers produced in extremely high quantities and used in particularly widespread and short-term (single-use) downstream applications to be identified as potential PRRs. The justification for the omission of such criterion

offered in the Wood&PFA report brings up the "risk" of "catching a large number of polymers." This justification has no scientific basis and appears to be unnecessarily biased towards "reducing the burden on industry" while neglecting the need to ensure high level of protection for human health and the environment. Polymers that are produced in high quantities and used in downstream uses prone to generating environmental pollution by secondary micro/nanoplastics should receive particular scrutiny and be subject to proper risk assessment followed by formulating and enforcing adequate risk management solutions. Dependence on the production volumes is a regular practice used in REACH for non-polymer substances. Making more substantiated decisions on the need to exclude or modify this criterion could become obvious once pre-registration (initial notification) data are obtained. Therefore, the final decision on the inclusion or exclusion of this criterion should be taken only after the analysis of notification data, but not before, based solely on unjustified assumptions about the numbers of polymers that would fall under this category.

Concluding remarks

We would like to conclude our analysis of the PRR identification criteria proposed in the Wood&PFA report with a quote from the same, which explains that the developed 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 (or indeed uncontrolled risks), but rather that the polymer could 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 should hazards be identified. It should be noted that in REACH all non-polymeric substances on the market are registered regardless of hazard.*"

In our view, PRR identification criteria should be formulated in a way that allows for the most reliable and inclusive identification of all potential PRRs. However, to ensure "proportionate" treatment, it can be considered whether differing data and testing requirements could be imposed depending on which criterion or criteria have led to a particular polymer's identification as a PRR. Collection of a minimum set of pre-registration (initial notification) data for all polymers (see below the response to agenda item 3-b) will be invaluable in testing and refining the proposed criteria as well as for defining the subsequent data and testing requirements for identified PRRs. While an eventual complete registration of all polymers, starting with those of highest concern, would have been the most reliable measure to ensure high level of protection of human health and the environment, collection of initial notification data, which can and should be accomplished within a reasonably short time frame, constitutes a practical first step to initialize polymer risk assessment process under REACH.

b) Are the identification and sameness of polymers sufficiently addressed? If not, what other elements should be considered?

Response:

The identification and sameness of polymers are sufficiently addressed in the report if judged based on the data and evidence which could be available to the authors of the Wood&PFA report. However, it should not be forgotten that the available data were rather limited. Therefore, it might be that other elements will need to be considered in the future, once more knowledge and more practical experience is gained. The approaches to the identification and sameness of polymers should be tested and further refined using the minimum set of pre-registration (initial notification) data which should be submitted for all polymers.

c) Are the proposed solutions for grouping of polymers acceptable?

Response:

The proposed solutions for grouping of polymers seem acceptable overall, however, the fine details may still need much further discussion and practical testing, which could then lead to revision and refinement of the proposed solutions. As has also been acknowledged in the Wood&PFA report itself, at the time of writing very little data were actually available which could be used in case studies on grouping. This data scarcity severely limited the authors' ability to test the proposed grouping approaches in practice. Therefore, before judging on the acceptability and completeness of the proposed criteria and solutions for grouping of polymers, it would be advisable to carry out and publicly present such case studies for grouping approaches using real datasets which should be provided by the industry. Here, collection of a minimum set of pre-registration (initial notification) data for all polymers would provide an invaluable resource to test the grouping approaches and could possibly lead to additional solutions and e.g. computational innovations in this regard.

Agenda item 3. Registration of PRRs

a) Is the subdivision in Type 1, 2, 3 based on molecular weight and related data requirements appropriate?

Response:

In the comments provided above, we have already explained why the threshold of <1,000 Da proposed for the Type 1 polymers may need to be higher in certain cases. Furthermore, for fluoropolymers a threshold of <1,500 could be more appropriate, and the thresholds for Type 2 and Type 3 might also need to be reconsidered for this polymer group.

Further, we emphasize that not only the MW_n of a polymer as such, but also its oligomer content and presence of reactive groups as well as of stability-preserving additives and impurities should be considered when determining the level of testing data requirements for a given polymer. For example, it should be considered whether polymers of Type 2 and Type 3 should also become subject to similar data requirements as for Type 1 in case their low molecular weight oligomer content exceeds an agreed threshold. The Wood&PFA document (p. 128) says that maximum data requirements set for Type 1 "could apply to higher molecular weight polymers (Type 2 and Type 3) if their initial assessment showed that more data was needed." We suggest that the steps and considerations applied during this "initial assessment" should be defined in more detail, and consideration of oligomer content should definitely be part of it. For ionic and surface-active polymers, the full registration data might need to be requested regardless of MW_n considerations, since the toxicity exerted by these polymers does not necessarily require an uptake but instead may rely on surface interactions only.

We also emphasize that data and testing requirements should also provide information necessary to understand the polymer's propensity to generate secondary micro/nanoplastics, also considered in relation to its physical form and expected downstream uses. Based on a rather unconvincing reasoning, as discussed above, this aspect has not been considered in the Wood&PFA report so far. However, it is imperative this this issue receives all due consideration during the subsequent development of REACH procedures for polymer registration, because micro/nanoplastics pollution resulting from polymer use constitutes an important contribution to human and environmental exposure, and the possibility of hazards resulting in adverse effects, both known and those yet to be identified as more scientific evidence becomes available, cannot be excluded at the moment.

For example, Table 4.5 (Table of environmental fate property data requirements for polymers) addresses degradation mostly from the point of biodegradation while abiotic degradation receives much less attention (e.g., through testing "abiotic hydrolysis as function of pH"). However, what may need to be tested and understood in the context of risk assessment for

polymers is also the polymer's propensity to generate micro/nanoplastics not only during the production (as here it can be argued that this is largely covered by the restriction for primary microplastics currently in development), but also during the use phase (e.g., product abrasion or leaching of fibres during textile washing) as well as at the end-of-life (e.g., during waste burning, waste water treatment, and following landfilling, littering etc).

As another example, in the same Table 4.5, for the parameter "Fate and behaviour in the environment (bioaccumulation in aquatic species, preferably fish)" it is stated that "this parameter will only be relevant to the lower MW polymers and oligomers. May be very difficult to achieve experimentally; not applicable to surfactants." Here we tend to respectfully disagree. Scientific evidence demonstrating that this parameter can also be relevant for micro/nanoplastics has already appeared. Micro/nanoparticles which could be taken up by the organisms can be generated also from higher MW polymers, hence the exclusion of this group by default cannot be justified.

Based on the same considerations, data requirements for mammalian toxicology should also include appropriate testing of micro/nanoplastics which could be generated from the assessed polymer following realistic use or exposure conditions. We would also like to draw attention to the fact that there could be additional toxicity endpoints which are currently omitted but should be given a particularly careful consideration. For example, these could include the effects of micro/nanoplastics in the airways but also in the gut (e.g., local irritation and potential immune responses, including dietary sensitization and inflammatory conditions) and, importantly, on the gut microbiota. The crucial role of microbiota in human health and disease has been increasingly recognized in the recent year, and several seminal academic studies have demonstrated the potential of micro/nanoplastics to disturb gut microbiota in mammals and fish. While this field suffers from lack of data and lack of systematic testing, generation of testing data as part of REACH registration process could provide invaluable contributions to understanding the significance of microbiota as an endpoint in hazard and risk assessment procedures.

The above-discussed considerations regarding the need to include testing of micro/nanoplastics apply to ecotoxicological property data requirements as well.

Further, the part 4.4.9 (Data requirements concerning uses and exposure) should also be reconsidered in light of the polymer's potential to generate secondary micro/nanoplastics. At the end of this section it is stated that 'there will need to be clarity about how to treat microplastics, which are being addressed in numerous other initiatives." Among the "numerous other initiatives" relative to REACH in particular, we are aware only of the ongoing process for restriction of intentionally produced microplastics. This covers primary microplastics but in no way addresses the secondary micro/nanoplastics generated by polymers during use and at the end-of-life. In our opinion, registration and risk assessment of polymers under REACH presents the only available opportunity to address secondary microplastics on a systematic and fair basis. This will allow to identify and enforce appropriate risk management options necessary to mitigate the adverse effects on human health and environment, which can only be expected to increase if this hazard area will remain unaddressed here.

b) Is the registration process as proposed making sense?

Response:

It is absolutely crucial that the proposed full registration process, which is proposed to be carried out for the identified PRRs only, be preceded by a pre-registration (initial notification) process where a minimum set of data should be submitted for ALL polymers currently present on the EU market. That is, including the so-called polymers of low concern as well as all other polymers along the suspected PRRs. These pre-registration (initial notification) data should be received by

ECHA and, upon potential removal of CBI-protected information bits, made publicly available and accessible, e.g., in a dedicated database. Submission of pre-registration data for all polymers will provide indispensable overview of polymer situation on the EU market. This area of substance use in the EU currently suffers from multiple uncertainties and unclarities. This general lack of knowledge necessitates generation of many unnecessary assumptions and results in large uncertainties even in the situations where clear and unambiguous answers could be obtained based on a rather minimal set of data, which are in any case already available to the producing and importing companies. For example, with pre-registration the prediction of total numbers of polymers would receive a definitive answer. In this regard it is also worth remembering that the predicted high number of chemicals expected to be registered under REACH turned out to be much lower in the end: from 145,297 unique substances/entries submitted as pre-registration intentions in 2008, only 22,973 unique substances have been finally registered under REACH as of September 2020.

The Wood&PFA document already states that the industry should retain the assessments they are making to decide whether their polymer is a PRR, in case these assessments may be requested by authorities later. This "recommendation" should be transformed into a solid requirement, especially considering that the minimal data necessary to understand whether the polymer is a PRR will be compiled and generated by industry anyway. Thus, relatively little additional costs will be required to submit and share these data, with large benefits gained in return. For example, availability of minimal pre-registration data for all polymers to government and public will help to ensure objectivity and transparency in making far-reaching decisions about identifying a polymer as a polymer of low concern (PLC), a polymer "in-between" or a polymer requiring registration (PRR). In contrast, having initial assessments performed by industry itself without any oversight by ECHA or other independent stakeholders like academics and NGOs bears a large potential for conflicts of interest. It is also not in line with the announced course at transparency and objectivity of chemical risk assessments carried out in the EU. Thus, pre-registration (initial notification) will facilitate enforcement and will also enable formulation of realistic and attainable timelines for subsequent analysis and full registration procedures. Further, systematic data collected in this way will also allow refining the cost-benefit analyses. The availability of minimal data set for all polymers will also help test and refine the grouping approaches and approaches to hazard assessment. The access granted to academic community bears particularly high potential to provide additional innovations in this regard.

The minimal set of data submitted during pre-registration should include all positions stated in tables 4.1 and 4.3 as well as any additional data necessary to make a decision about PRR identification. For example, it should be ensured that provided data cover oligomers content; elemental composition; reactive groups; identity, hazard classifications and levels of stability-preserving additives and impurities; degradation products and propensity to generate micro/nanoplastics; production and import volumes; downstream uses categorized by lifetime frames (e.g. single-use, short time, durable), dispersibility (for example, polymers used in cosmetics or food are highly dispersible), or exposure to highly abrasive conditions. It should also be reported whether any recycled raw materials are used or are expected to be used in the production of this polymer in the future. Recycled materials may be more prone to contamination and this may require special treatment. This aspect has not yet been discussed in the Wood&PFA report, but might require more consideration in the future.

The often-cited principle of REACH legislation is "no data no market." To adhere to this principle, the initial focus of polymer registration process under REACH should be dedicated to initiating and completing the pre-registration (initial notification) process as soon as possible. Sharing the available minimal data by industry with ECHA and public will provide the necessary basis for reliable analyses and predictions regarding polymer use and the real numbers of polymers that will be covered by different full registration scenarios, and will also facilitate further development

of computational methods for hazard prediction and support of grouping approaches. Submission of pre-registration data and PRR assessments will also enable ECHA to control the correctness of the processes used to assess whether the polymer in question requires full registration or not, and this framework will provide transparency for the academic community and the public.

c) Is there support for focussing on Scenario 1 (Registration of PRRs only)?

Response:

We emphasize that many additional benefits of registration under scenarios 2-4 compared to scenario 1 have not been explicitly considered in the Wood&PFA report. These include, for example, informational benefits from getting a complete overview of all polymers, which could, e.g., lead to designing better waste management processes and facilitate more efficient and faster transition to circular economy. There is also a possibility that additional, previously unknown hazardous properties, toxicity targets, or environmental fate peculiarities could be identified for polymers previously considered to be of low concern (as has been recently experienced, for example, by Canadian regulators). This could trigger the necessary risk assessment and result in the establishment of risk management procedures providing for better protection of human health and the environment. Therefore, we propose that elements of Scenario 2 should be integrated alongside the Scenario 1 through the establishment of a pre-registration (initial notification) requirement for all polymers. Important to note here is that both Scenario 1 and Scenario 2 have benefit/cost ratio above 1, which indicates that significant benefits are still to be gained in Scenario 2 as well, even within the limited scope of benefits considered in the Wood&PFA report. Since it can be expected that pre-registration (initial notification) of all polymers will be associated with significantly lower costs, while still providing many tangible benefits, it can be assumed that the final benefit/cost ratio will be even higher.

4. Cost-benefit assessment

a) Are the elements and figures used in the cost-benefit assessment appropriate and reflecting the possible true costs and benefits?

Response:

The general observation, also acknowledged in the Wood&PFA report, is that currently much more data are available for costs, while benefits often remain unquantified or quantified with large uncertainty, and thus are almost never properly taken into consideration. The likely underestimation of benefits has been acknowledged in the Wood&PFA report on several occasions. These aspects should receive more attention in the future. In addition to the positions already dealt with in the presented analysis, we suggest that the hazards of generated micro/nanoplastics pollution should also be considered and where possible quantified. Consequently, the benefits resulting from reduction of macro/micro/nanoplastics pollution in the environment should also be considered and where possible quantified.

b) Any additional information or recommendations that COM should take into account in its Impact Assessment?

Response:

Environmental pollution by macroplastics, as well as generation of secondary microplastics and nanoplastics and the resulting widespread pollution, currently do not receive appropriate consideration in the presented Impact Assessment. This is inacceptable. Various polymers and a

multitude of downstream uses have been clearly identified as the most likely and significant contributors to the rising environmental pollution by micro/nanoplastics. This resulting exposure potential and the associated human health and environmental hazards should be taken into account and carefully considered for all polymers, supported by generation of appropriate empirical data or modelling estimations where appropriate. The potential for contributing to micro/nanoplastics pollution is also one of the main reasons behind the need to include the criteria of production volume as one of the criteria for identification of PRRs. At a minimum, sufficient data should be provided during the pre-registration (initial notification) process. The need to use all available means and approaches to mitigate the micro/nanoplastics pollution of our environment justifies the inclusion of micro/nanoplastics exposure- and hazard-related considerations into risk assessment of polymers. Reduced generation of micro/nanoplastics pollution should be firmly included among the targets pursued by the subsequent risk management solutions.