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, 26/01/2021
CASG-Polymers/01/2021

DRAFT MINUTES

2nd Meeting of REACH and CLP Competent Authorities Sub-Group on Polymers

16 December 2020 14:00 – 17:30

Webex-Meeting

Minutes CASG – Polymers 16 December 2020

Attendance

Member States	Member States: AT, DE, DK, ES, IT, FR, NL, NO, PL, SE
Observers	A.I.S.E., ALIPA, CEFIC, ChemSec, DUCC, ECETOC, EEB, EuPlastics Converters, FEICA, HSI, IBO, ISOPA, PETA, Plastics Europe, Polyelectrolyte producers group
ECHA	
Commission	DG ENV (Chair), DG GROW

These minutes combine statements made verbally made at the Webex as well as in the chat.

CASG-Polymers 16/12/2020

1. Adoption of agenda

The chair welcome the CASG members and announced that DE had suggested to discuss polymer sameness under AOB if time allows. The agenda modified by that point was adopted.

2. Adoption of the minutes of the 1st CASG meeting Sept 2020

EEB said that they had sent comments by email. The chair responded that those had not been noticed so far, but that they will be acted upon still.

3. Identification of Polymers Requiring Registration (PRR)

The chair explained that COM had modified chart 3.2.of the Wood report on the basis of feedback submitted by members of the CASG-polymers and based on discussion among COM services and ECHA. COM briefly explained the flowchart (see Annex and reasoning therein) and the reasoning for changes made, as laid down in the background document. The flowchart was intended as a new basis for discussion but could still be amended.

a) In-depth discussion on necessary criteria for identifying PRRs

A.I.S.E. commented (via chat) that the explanation on the first box is not strictly correct. It says that the Australian PLC criteria exclude all GHS classifications, but this is not entirely correct - certain classifications are allowed (Flam. Gas Cat. 2, Acute Tox. oral/dermal/inhalation Cat. 5, Skin corrosion/irritation Cat. 3, Asp. Haz. Cat. 2). Not an issue for EU CLP, but just for full correctness of the document. In addition, classifications should be referred to as CLP classifications, not GHS. The chair acknowledged it is better to refer to CLP and that changes can still be made.

DG GROW added that the short introductory presentation did not fully reflect DG GROW's position. Mainly, DG GROW is of the opinion that exposure considerations can be introduced into the flowchart. The chair agreed and explained that she intended to still explain the different opinions shown as options on page 2 of the background document.

ISOPA questioned if this is the right process of identifying polymers that should be registered. According to article 138(2), only polymers that pose a risk should be subjected to registration. DG ENV responded that its reading of article 138(2) is different. But the position is noted.

PPG added that the Canadian scheme still has registration requirements for polymers of low concern (PLC), which are correctly called Reduction Registration Requirements polymers (RRR) in Canada. PPG added that Wood's proposal was just an unrealistic easy way out.

b) PRR-identification flowchart

How to consider exposure

PPG remarked that what is being proposed here is to look into an elite group of polymers that should be subjected to registration. What will we do with UVCB, because this is what polymers are about? Canada does not require environmental classification, and most of the polymers we are talking about here are about environmental hazards. Exposure should be the principal criterion to require registration.

ChemSec shared their opinion that following Article 138(2), COM should propose a legislative proposal, based on a report, and the report should look into the risk polymers represent. But that does not mean that a legislative proposal could only be based on risk consideration. The chair agreed that this is also DG ENV's interpretation and DG ENV added on the chat that article 138(2a) is just asking COM to publish a report comparing the risk of polymers compared to that of other substances.

CEFIC recommended that COM should look into costs and benefits of exposure being one of the PRR-identification criteria, as in their view the benfit of registration is questionable when there is little or no exposure.

The chair clarified that COM did not propose to completely leave exposure aside. But that the proposal is to leave exposure considerations mostly aside during the stage of identifying PRRs, and then consider it later in the context of the information requirements for polymers. That would be consistent with how it works for other chemicals. DG ENV added that the flowchart takes exposure into consideration in one step already, namely where polymeric precursors are exempt from becoming PRR.

DE intervened to say that exposure is about the manufacturing stage, rather than exposure during the life cycle of the product. DE clearly preferred option 1.

ISOPA suggested that the term PRR in the flowchart could be changed to 'potential PRR', and that exposure-based consideration could then be taken in to account at the end.

CFE commented via the chat that they strongly favoured option 2, to take exposure into account as early as possible should ensure that animal testing can be minimised.

HSI and PETA-ISC (via chat) supported CFE's comment.

EEB commented that high production volumes are an indication of exposure and that they should be considered as criterion for registration and for substance evaluation.

PPG stated that they favour option 2. Production volumes do not have anything to do with exposure.

CEFIC explained their view that the overall scheme should be more efficient with taking into account exposure. When looking at the existing registration scheme for non-polymers, it is not considering

exposure sufficiently and appropriately, too much testing is done due to “box-ticking”. Tonnage does not impact on exposure, volume does not even go into the exposure calculations (for human health). Cefic proposed a change for what they called the ‘outdated’ system of Standard Information Requirements in REACH: base-set, do risk assessment, then trigger more extensive testing. There are many ways to do this e.g. risk matrix, as is already done. Option 1 is different from what we are traditionally doing for non-polymers. The chair reacted in saying that if exposure is to be taken into account, it should clearly be done before testing is triggered.

NO stated that it supports option 1.

SE favoured option 2 to include exposure. However in a different sense as industry argues, i.e. to make a polymer PRR based on exposure. Polymers are known to be found in the environment because of their use. If one would not include that in the PRR criteria, polymers that are already identified as releasing microplastics into the environment would not be reported because they might not have the other properties of a PRR.
SE added via chat that exposure is normally handled through a registration of a substance in REACH. However, the Wood-report does not cover this aspect as a PRR criterion. Sweden supported the option 2 to include exposure as a PRR thus polymers are known to be found in the environment as a consequence of downstream use, and debris from that.

The chair informed that a document was uploaded to CircaBC for information about the activities ongoing by COM and ECHA on microplastics. COM does at the moment not intend to consider the fact whether a polymer could result in microplastics as part of the PRR criteria.

ISOPA, ALIPA and FEICA expressed their support for option 2 (on chat).

DG ENV raised the question via chat how to take into account variability of uses, new uses, foreseen uses in a decision-making process for registration based on exposure.
CEFIC responded that it should work the same way as done already for uses communicated etc.

DK, NL, BE and FR supported option 1 via the chat. FR added that there should be a hazard based approach for deciding which polymers are meeting the PRR criterion.

DE supported not to include the issue of microplastics in the PRR scheme.

ChemSec observed that it does not make sense to strictly vote for option 1 or 2 only, because everyone puts his own value on each of the options. The important thing is how we phrase each of the options.

EEB agreed that we need much clearer definitions before we start collecting opinions on who agrees with which option.

ChemSec and SE suggested to use exposure as a trigger for meeting PRR status.

DG ENV clarified that it was initially proposing to include a safety net criteria for registration, but in the flowchart it is proposed to substitute this criteria by the possibility to subject a non-registered polymer to a request for specific information by Member States on the basis of an identified concern (comparable to substance evaluation (SEv). The chair added that DG ENV acknowledges the

safety net is not something that registrants could have applied, only authorities. A concern could be identified on the basis of the assessments done by industry on why a polymer is not PRR that should be shared with ECHA, so that MS or ECHA can double-check the information and decide on the course of action.

DE commented that the proposed SEv-like mechanism would be a high burden for authorities to look into all datasets. They also felt this approach would create an incentive for industry not to consider a polymer as PRR. SEv should not be part of identification of PRRs.

SE shared DE's concern, and wondered if the proposal to only include SEv as a safety net criteria instead of a PRR criteria wouldn't shift the burden to authorities instead of ensuring the burden is placed on industry.

ISOPA stated that for (non-polymeric) substances that are not subjected to registration, there is no SEv. PLC should not undergo any notification. ECHA may end up with horrible number of submissions. The chair clarified that the intention is not to treat polymers in the exact same manner as normal substances. The idea was to come up with mechanism that allows authorities to look into polymers into more detail, if justified.

ChemSec emphasised the need for industry to self-assess whether a polymer is safe. They supported the notification mechanism proposed by COM. The chair added that the intention of SEv is not to force substantial additional data generation for the sake of it, but that MS would need to submit information that justifies their concern and convince other MS of that, like happening in SEv today.

DG GROW shared that they have doubts how SEv can be involved. Normally, compliance checking of the registered substance is the first step, and substance evaluation might follow if there are grounds for it. REACH provides other options (e.g., SVHC identification) for MS to act based on concerns, and these mechanisms do not depend on registration.

Plastics Europe added via chat that the Plastics industry is not avoiding responsibility for the microplastics issue, as can be seen from its support of various clean-up schemes, but they think this registration process will not benefit this since they recommend either safe recycling or safe disposal at end of life. We need to give greater effort to ensure that this recommendation - in Safety Data Sheets - is met and not abused. MP efforts are well advanced elsewhere and a registration scheme which will confirm safe end of life disposal is unlikely to help the process.

CEFIC shared their view that people are overestimating what the data will look like that would be notified as proposed in the flowchart under 'evidence that a polymer is not PRR'. CEFIC is concerned that we are creating a huge graveyard of data that ECHA will not be able to use. We should only do this if we know that we can use the data correctly. The chair agreed that no one will be helped if we create a graveyard of only basic data, but what we intend is to create a database with assessments and explanations how a company concluded that a polymer should not be registered. Not clear yet how this assessment should be performed, COM are open to suggestions.

CFE commented via chat that whether non-PRRs are pre-registered or not, they emphasise there must be a solid basis for raising concerns that are to be further investigated, in particular if there is the potential for new studies on animals to be required. There shouldn't be free rein for any polymer

to be brought to the SEv process without a solid basis for concern relating to the intrinsic properties of the substance and the potential for toxicity.

SE supported the option 1 to have a pre-registration of all polymers including volumes. Provided data could be enough to state why the polymer is a PRR or not. This is to verify how many polymers exist within the EU and to make it possible for companies having the same polymer, to find each other. It is also a question of transparency and supervision. The reporting system should be created in a way which would make the registration easy. This could be done using guidelines for different types of polymers.

NO supported SE in this comment.

CEFIC asked how useful the pre-registration database was for authorities? Or the CLP inventory?

DG ENV as well as ChemSec replied that the pre-registration database was of little use for the authorities, but the CLP inventory is very useful and is used by ECHA/MS for example when developing RMOA.

Polymer degradation – options 1 and 2 how to take it into account

PPG commented that related to polymers, one should not talk about biodegradation but just degradation, because physical degradation is the main mechanism.

CEFIC shared their concern that a double regulation could result from this degradation criteria. SVHC should be caught by current regulatory set up. If we talk about polymers that degrade into SVHC, is this an appropriate approach? Degradation is difficult to establish. The use of the word 'likely' in the flowchart is not precise enough Fluorinated polymers are excluded in some countries. The chair agreed that there may be quite some differences within the class fluorinated polymers, some can degrade to substances of concern like PFAS, others not. The chair agreed as well that 'likely' should be replaced by more precise language, once agreed.

EEB preferred option 2. But added that the SVHC list is too narrow in defining substances of concern.

ISOPA stated that degradation tests used today are not applicable for polymers - only for substances.

ChemSec supported option 2 as well (on chat).

DE also supported option 2. There are hazardous substances that can be formed through degradation. To consider degradation is in line with the safe & sustainable–by-design principle.

A.I.S.E. reiterated that concept and remarked that biodegradation is currently phrased in the chart only as a negative property leading to PRR status, but it could, in fact should, be considered as positive criterion as well, e.g. the potential for easy and complete biodegradation (not 'P') could be a positive criterion in the flowchart, e.g. as part of exposure considerations, or as a factor to modify/reduce the testing requirement - drawing parallel with thousands of natural polymers degrading in the environment.

DG ENV added that the main issue is about how we define biodegradation. Some talk about ultimate degradation others about degradation into SVHC. A report was published yesterday by the Group of

Chief Scientific Advisors on Biodegradability of Plastics in the Open Environment, which the COM will still look into and consider for this exercise.

PPG agreed with A.I.S.E. that degradation and elimination are extremely important in the flowchart.

SE explained that they suggested to add the issue about PFAS to the chart. This group of substances is important. But the definition of PFAS is not only about small chemicals, also polymers are concerned as PFAS according to OECD.

NO supported option 2 that all polymers which can give rise to degradation products of concern should be PRR. If degradation should be a criterion they pointed out the need to carefully define the term "could give rise to".

DK added that they supported option 2. Not only PFAS and PFACs are of concern. All SVHCs are of concern. It is in the definition.

FR stated that they support option 2 but wondered how to deal with polymers with no data or not enough data about degradation products.

ISOPA would prefer a rewording to this box to refer to the chemistries that might give concern.

ISOPA added that criteria for biodegradation are very broad and vague. If they go through their portfolio, should they undertake studies for everything and decide which polymer meets which criterion? Also, they recalled that as mentioned by ECETOC in their report existing test methods cannot be applied to polymers. The chair said indeed the intent is to provide the registrant a stepwise approach to assess whether a polymer should be registered or not. The idea is not to trigger many studies for the process of PRR identification. That may therefore also entail that, in case of doubt, industry should err on the conservative side and consider that something is PRR. As for methods not being applicable to polymers, the chair acknowledged that this requires discussion but suggested we leave for a future meeting dealing with data requirement, and now focus on the criteria for PRR identification.

ChemSec reminded the group that we are talking about which substances are to be registered, we are not talking about a ban. We are talking about providing proper information on a product.

FEICA responded that even if we are talking about registration and not bans, we would like to remember that downstream users customising polymers will become registrants of the polymers they customise. For an SME, having to face a too expensive registration process (hiring external consultants, performing testing, allocate resources) could have a result similar to a ban, since it would no longer be possible from a cost/benefit point of view to customise those polymers to meet regulatory and customer requirements (for example, to achieve energy efficiency goals). FEICA is not against the assessment of polymers following the decision flow chart, and will of course contribute to the discussion as they did so far. FEICA was also raising the point that downstream users will become registrants for the first time, we have thousands of customised polymers. This needs to be taken into account in the process, since it could indeed lead to the disappearance of customised polymers, which bring benefits to society. Of course, this can be discussed in another part of the process, but would indeed be very close to a ban if not taken into account.

Precursor to other polymers or articles handled like intermediates

DE stated that they could agree to exempting polymeric precursors, if a closed system is guaranteed. Such exemption should only be possible for industrial uses. By reverse logic, if exposure cannot be excluded, registration is needed.

DK agreed with DE and shared their opinion that the word intermediate is not necessarily wrong. An intermediate can be isolated or non-isolated.

CEFIC recalled that polymers are not as reactive as monomers, and are mostly used in products where solvents and monomers drive the hazard. If a product containing polymers is already handled safely, it is not necessary to request closed system as for monomers because the polymers are not as reactive. The difference to "strictly closed system" intermediates is that polymeric precursors are well characterised in their hazards and risk assessment can be done, while for intermediates the assumption is that RA cannot be performed, hence exposure has to be as low as possible.

ISOPA stated that polymers are not handled as pure substances, they are handled as mixtures. In that sense, the term intermediate is inappropriate to apply, in their view. Polymers are mixtures containing monomers, of which the risk is already controlled. DG ENV asked why industry wants to exclude them. Polymers are mixed with monomers, which are already subjected to registration. ISOPA simplified for illustration that a mixture containing substances A, B and C, which are all registered, they do not understand the value of registering the polymer A-B-C. DG ENV intervened to say that the polymer A-B-C could have different phys-chem characteristics, like vapour pressure for example, that could lead to different effects or exposure.

ISOPA responded that all polymeric products would have a lower vapour pressure than their components.

DE considered that polymer precursors are not necessarily less hazardous than the constituting monomers. Additionally, the lifecycle of unreacted monomers in polymers is insufficiently covered in monomer registrations.

EEB supported DE's comment. Information on monomers content in different types of polymers is rarely, if ever, provided in monomers dossiers. In addition to DE's comment, also stability-preserving additives should trigger polymer registration if classified as hazardous.

The chair asked ALIPA to comment about polymeric precursors. ALIPA explained that the precursors have the same reactive moieties like the monomers. For that reason, the precursors are also classified like the monomers. These precursors already have an SDS showing this classification and they do not leave the industrial process before being polymerised into much larger polymers or even articles. Registration of the polymer would not change its safe use (as the monomer drives the hazard).

Other criteria

EEB asked whether they can still send written comments about the other criteria, which the chair confirmed. EEB raised that there is no clear definition for the PLC criteria referred to in the first box of the flowchart. Not clear why COM wants to take Canadian criteria, while at the same time saying they are not totally appropriate. Not clear why polyesters should be exempted. EEB also questioned

if the criterion surface activity can really replace the criteria for anionics, nonionics and amphoterics, as not all those polymers are surfactants. On molecular weight criterion, does it include oligomer content? They believed they are two different criteria.

The chair responded that COM intends to consider oligomers, probably in the same box as the molecular weight criterion, not separately, just as was suggested by Wood. EEB still had a question on the cationic criterion. Also, there is need for a clear definition for degradation into substances of concern. They wondered whether microplastics formed through degradation could be such a substance of concern. Finally, on the 11 hazard classes considered now, polymers may have other hazardous effects, e.g. interactions with the gut walls or with the gut microbiota. This should not go out of consideration.

DE supported the EEB's comments. On precursors, DE added that they are not in all cases less hazardous than their monomers. DE suggested that the molecular weight criterion could go further up on the flowchart. Lastly, DE raised that the content and substance identity of the monomers of a polymer should in their view also be a PRR criterion.

CEFIC wondered what that would add and questioned whether DE's concerns should not be covered in the monomer dossier.

4. Pros and Cons of a Pre-Registration or Notification of Polymers

ChemSec shared their opinion that the proposal for notification is a good set-up, that once the registration threshold has been set, all polymers will be registered and that, if you don't register, one should prove why that is so. This should be as transparent as possible.

DK raised that they are in favour of a notification scheme. The conclusion whether a polymer is a PRR or not should be clearly explained and made available by default, and not under request only.

NO agreed with DK. If a polymer is defined not to be a PRR, substance identification and documentation on how this conclusion was reached should be notified to ECHA. The information should also be available to Member States in order to consider whether risk reduction measures (RMM) could be proposed.

The chair said that industry's proposal (shared separately only with COM) is to indeed document why a polymer should not be PRR, but that the information would be kept on file by the company and available for authorities to check only on request in an inspection scenario.

DE stated that they clearly prefer a notification to ECHA by default, instead of kept in-house by companies. For reasons of administrative ease of access for Member States. DE felt that the ECHA database of notifications might help ECHA to define or refine sameness criteria. ISOPA disagreed with that, as CBI would prevent that.

CFE stated that a pre- registration is the most obvious way for ECHA to see what polymers go for registration and it should help avoiding duplication of animal testing. PETA-ISC supported CFE in the idea of a pre-registration system for PRRs only.

The chair remarked that also PLCs in other jurisdictions have limited registration requirements. ISOPA replied that the data required for PLC assessment is only applicable to new polymers and very different from that for grouping - and different groups of polymers rely on different parameters for sameness.

CEFIC stated that a notification would need an agreement on polymer sameness upfront. It will require CBI, hence the information cannot be made public.

CEFIC observed that there are two reasonings being discussed why a notification could be useful. CEFIC added that notification that should be useful for ECHA for grouping purposes would need to be quite detailed and hence require a lot of effort and time from companies. ECHA would then have a lot of information and would struggle to make sense out of it. Also, such a system would provide no motivation for ECHA to make groups as large as possible and reduce animal testing.

Plastics Europe commented that if companies are to submit information on their conclusion that a polymer is not a PRR, essentially we are asking for a submission on substances that are excluded for registration. For non-polymer substances, this does not occur. The chair agreed this is something new but said this happens for PLCs in other jurisdictions outside the EU already. Plastics Europe agreed that it is the case e.g. in South Korea. For polymers, importers that have submitted registration dossiers for monomers, we would be asking them to submit the same notification/registration for the same product, so two registrations for the same substance, where outside the EU they would not be subjected to this double-registration.

ISOPA raised that upfront such a notification, an agreement of substance ID would be required for the purpose of grouping. But substance ID is still an unsolved issue for CBI reasons. The company notifications to ECHA explaining why a polymer should not be PRR would not be grouped, they would be submitted company by company and hence result in a huge database in which it is not easy to identify similar polymers. ISOPA explained the multitude of possible grades of a polymer would likely form an issue, and lead to notification of each batch produced. They called for a practical approach.

ChemSec added that one advantage with public notification is that it will allow authorities to identify similar polymers. Information gathering should not take years. Notification should not require animal testing, because it is about characterisation of the polymer. Testing data, which has anything to do with hazards, should be made public. With regards to CBI, it should not be used as an excuse not to share anything.

ECHA shared their experience of having collected over a million notifications in the ECHA database, so they know how to deal with big amounts of information. About making information available to Member States, if given adequate resources, ECHA have the technical capabilities and experience (e.g. SCIP database) to do so and consider this in the current situation part of their core tasks. But it would be important for ECHA to know what is what. Industry should be responsible for grouping, and more consideration is needed here.

The chair asked whether industry in the meantime had acquired any more experience from registering polymers under Korean REACH.

AT asked via chat if the Korean polymer registration procedure could be used for a notification scheme? This provides for pre-registration on the basis of the monomers. The sameness of the polymers is based on the monomer(s) for polymerisation.

DE added that, nevertheless, the current criteria do not seem to be sufficiently scientifically substantiated. Thus, a pre-registration could decrease uncertainty in defining the criteria to identify PRRs (of course, the "right" data needs to be collected).

Plastics Europe offered that in their experience, the key piece of data is molecular weight. This was all claimed confidential. In the case of some polymers registered in Korea, Korean authorities concluded that there was nothing registered with a similar composition.

PPG stated they also have experience with Korea. CAS numbers are used for this. The number of polymers can be associated with the group of polymers that are of concern, when they are not. Pre-registration is necessary, and it seemed impossible to do this without consortia. They trust that ECHA has the capability to handle this. PPG asked whether if polymers are not going to be registered, it means that import is open?

EEB added that pre-registration in Korea is only requiring CAS number and Legal Entity information and is hence not useful. Then Korea considers oligomer content (via GPC data) and cationicity of a polymer.

DG ENV clarified that in our PRR-identification scheme we talk only about notification for those substances that do not fulfil PRR criteria. ENV added that developing a substance IOD system will be difficult, but the pilots might help. It could be one system for all, or more tailor made per sector. Pre-registration is a different discussion, this comes once the registration process has to be decided.

CEFIC informed that there may be different classifications under the same CAS number. Also, what happens if they have 140 polymers in a group, do they need to submit 140 different notifications?

The chair responded that in that case, hopefully one notification would suffice.

EEB reacted to ISOPA's comments in saying that industry should be grouping polymers for which they reach the conclusion non-PRR.

EEB further commented on pre-registration, that there is a need for transparency. There are many ways of claiming CBI. Competent authorities need to have access to information. Only such an approach would met the transparency principle of REACH. But downstream users, workers, academia, etc. should have access to the information as well, not only competent authorities. Also competent authorities dealing with waste, recycling, etc. So the system should not be conceived only for REACH competent authorities.

CEFIC added that indeed, they proposed that the industry sector groups develop grouping and then discuss with ECHA if they are reasonable, before starting more testing for registration. But then one would not need a notification of non-PRRs to ECHA.

FR stated (on the chat) that, as a general comment, regarding the objectives of REACH, they feel that a notification or a pre-registration for all polymers with data already available and sufficient to

assess whether the polymer is a PRR or not would be practical for enforcement activities. And it would bring an overview of the polymers and uses in the Union. It would also allow to assess the effectiveness of the registration of polymers, drive further initiatives on polymers matters from COM, Member States and agencies (for example with regard to new polymers). It would also allow companies to take contact in order to possibly make common registration. They noted that the information would be about physical and chemical data and not about toxicity or ecotoxicity, which would involve animal testing. About CBI, polymers are not final materials. It is likely that there would be less confidentiality matters there.

DE supported FR.

CEFIC responded that the FR suggestion would mean a simplified registration scheme for all polymers, not what is being described in Article 138.

ChemSec reacted that Article 138 leaves it to the regulators to develop a registration scheme. CEFIC agreed but stated that the legislation describes the intent of the legislator, which is to be adhered to by the administration/regulator.

A.I.S.E. added that the Chemicals Strategy for Sustainability also talks about registration of a sub-set of polymers.

AT commented that also Article 138(2) talks about registration of certain types of polymers.

5. Update on CEFIC-ECHA Pilot projects

ECHA gave an update on the status of the 5 cases studies. The purpose is to verify technical grouping principles safeguarding CBI, grouping principles for different chemistries and to evaluate existing hazard profiles of the groups. ECHA agreed to upload the presentation on CircaBC for the CASG-members. ECHA stated that while there is progress, there are no conclusion of the project yet, and the planned timeline of May for results from the project might prove challenging.

There are terminology issues to be solved still, e.g. pre-polymers/reactive polymers/polymeric precursors; polymer product/polymer substance.

Grouping can refer to grouping and read across, but can also refer to grouping of chemicals to define a substance. Facilitated grouping is seen as important in reducing the number of registrations.

Ongoing reviews. The initial focus of the ongoing reviews has been on the representativeness of information, possibilities for grouping, impact of CBI and on availability of hazard info. As for the timeline, it is foreseen for end of February to finalise general learnings of two sector groups, April for the discussion of the findings and in May the general learning for the three remaining sector groups.

Common theme: more clear definition of the purpose of each of the different pilots required. Pilot studies will have to be a desk exercise, i.e. no time to do more testing.

Case studies:

- Relative data rich group: alcohol ethoxylates. Starting point: HERA report in RA of AEs. Composition relatively well understood. How to deal with trends in a property within boundaries of composition. Expansion of group boundaries.

- Data poor(er) group: amino resins. Starting material understood but need some clarifications of the manufacturing processes. Consultant report with an assessment of the available data. Complexity in the polymer life-cycle.

- Data poor group: epoxyresins. Grouping based on process applied, synthesis, reactive groups. Bottom-up approach: monomer > NLP (oligomeric fractions) > polymer high MW (solids). Considerations on bioavailability and toxicity drivers. Impact of variation in backbone? The sector group argues for a pre-registration consultation with ECHA to get agreement on the grouping into unique polymers for registration.

Grouping at substance level:

- How could we handle large groupings of structures within one polymer group? Different classifications depending on particular structural features.

- How do we generate and manage the necessary data (for extrapolation) within the group? REACH allows us to ask for standard information.

Cefic welcomed the engagement of ECHA, and highlighted the importance of its feedback. FormaCare clarified they have understood that the data presentation on the amino resins has to be done in a different way as expected, which may be doable, but they noted the challenging timelines.

EEB wondered whether the alcoholethoxylates are a good case study because most of them are low MW substances.

ECHA responded that they are still a good case study because the chemistry and a number of hazards are relatively well known. As such, it gives an indication of the possibilities and consequences of different ways of grouping as well as the possibilities for read-across.

CFE asked ECHA if they think this exercise will allow to get a much better understanding of what a polymer is and what data ECHA would like to have?

ECHA explained again that the purpose of the project is to find chemical or physico-chemical properties that can identify groups of polymers within which the hazard profile would likely be the same. So that one could have confidence that group members could be covered by the same dataset.

AOB: Sameness of polymers (DE request)

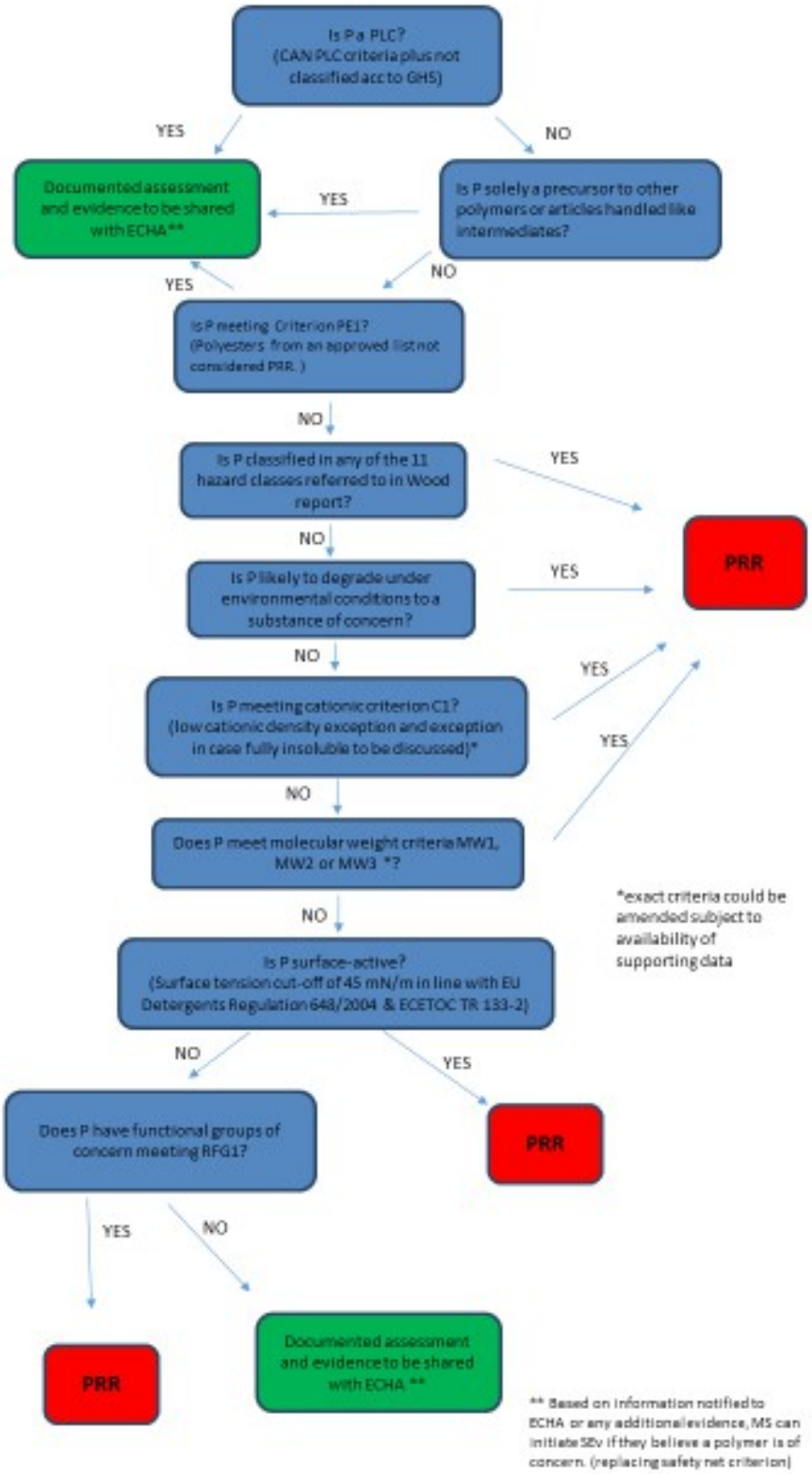
This topic could not be discussed because of lack of time

Next steps:

COM will require some time to think about the most sensible next steps, so they could not yet announce the date for the next CARACAL subgroup. Likely in the month of March, via Webex again. The proposed agenda items could be substance identity, sameness and information requirements for PRRs. After some discussion regarding how much time might be needed for these three items, DG ENV suggested to focus on information requirements first, and maybe deal with substance identification and sameness in a subsequent meeting, as these items are also the object of the CEFIC-ECHA pilot project. PRR-identification flowchart could also be discussed at the next meeting, if necessary.

The chair invited the group to send further written feedback on the PRR-identification flowchart by end of January, and any input on the topic of information requirements for polymer registration by 15 February.

New Figure 3.2: PRR Flow chart proposal



Annex

Reasoning

Is P a PLC? (CAN PLC criteria, plus not classified according to GHS)	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.
Is P solely a precursor to other polymers or articles handled like intermediates?	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.
Documented assessment and evidence to be shared with ECHA**	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.
Is P meeting Criterion PE1? (Polyesters from an approved list not considered PRR.)	PE1 criterion from Wood report. Polyesters from an approved list do not need to be PRR. List can be reviewed still.
Is P classified in any of the 11 hazard classes referred to in Wood report?	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).
Is P likely to degrade under environmental conditions to a substance of concern?	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.
Is P meeting cationic criterion C1? (low cationic density exception and exception in case fully insoluble to be discussed)*	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.
Does P meet molecular weight criteria MW1, MW2 or MW3? (cut-offs to be re-discussed)*	Criteria MW1 – 3 are from Wood report. Exact cut-offs could still be amended subject to availability of supporting data.
Is P surface-active? (Surface tension cut-off of 45 mN/m as in EU Detergents Regulation 648/2004 & ECETOC TR 133-2)	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, amphoterics and nonionics.
Does P have functional groups of concern meeting RFG1?	RFG1 is the criterion of the Wood report.
PRR	Polymers defined as PRR following the flowchart should be registered. Where the polymer is directly related to already registered structures of lower MW, e.g. NLP substances,