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ASMoR Comments: CARACAL paper on the Reform of REACH Authorisation and Restriction Processes

February 2022

ASMoR[1] welcomes the opportunity to provide its views on the reform of the REACH Authorisation and Restriction including the potential amendments presented by the Commission to CARACAL on 27 January 2022 (CA/03/2022). We understand that the purpose of the discussion at this stage is to refine the options to be analysed in the impact assessment. We also note that the Commission expects that through this process a **'preferred option'** will crystallize, taking up elements of different options. We will therefore comment on elements proposed by the Commission and on other aspects that may help achieve a streamlined and more effective management of chemical risks. In that regard, we recommend reading this document in conjunction with ASMoR's document on regulatory efficiency, available here.

The overall reform of chemicals risk management cannot be assessed without taking into account the Commission's ideas regarding an **extension of the Generic Risk Approach** (GRA) and the **introduction of the Essential Use Concept** (EUC). We commend the Commission for including references to both GRA and EUC in the CARACAL paper and will briefly cover these aspects, too.

I. Overview of Comments and Suggestions

Taking into account the Commission's questions included in the CARACAL paper, ASMoR herewith summarises its comments and suggestions.

As per the CARACAL document, the Commission anticipates that none of the three policy options presented in the paper will be adopted as such, but that the 'preferred option' will take up elements from the different options presented. We therefore believe that for an effective Impact Assessment, it will be important to rather **analyse the costs and benefits of the individual elements raised by the Commission in the different options**, than to treat the elements as if they were parts of specific policy options. The Impact Assessment should also **assess the potential impact of chemicals risk management decisions on other policy objectives** (e.g. the circular economy, prevention of climate change).

A. Proposed Reform of the Candidate List

ASMoR believes that adding **too many purposes to the Candidate List** will not allow it to be used in a proportionate fashion. Authorities may in the future be interested in triggering one of the obligations

[1] The Alliance for Sustainable Management of Chemical Risk (ASMoR) is an alliance of more than 30 members that develop common positions on the future of EU Chemicals Risk Management including the possible role of the Generic Risk Approach (GRA) and the Essential Use Concept (EUC).

that would be linked to the Candidate List, but not the other obligations. Proportionate decision-making will become difficult, if not impossible. We suggest the **use of other targeted tools to achieve legitimate objectives.**

Downstream User Notifications: Better tools than the Candidate List should be identified to gather information from downstream users (DUs). The data-gathering exercise should be **limited to information that is needed and relevant** to a timeframe during which the information is needed.

Candidate List as tool to prioritise substances: While we support **decoupling the Candidate List from Authorisation** (see further information in section E), we note that other tools already exist to prioritise substances that may be regulated in the future. The **Assessment of Regulatory Needs** (ARN) section of the **public activities coordination tool** (PACT) could serve that purpose. It is for example not clear why the inclusion of a substance, for which an OEL under OSH should be developed, would require the inclusion on the Candidate List first. It is neither clear, why substances for which risk management measures have already been implemented at EU level should be added to the Candidate List.

Proposed fee system for SVHCs: ASMoR Members **oppose the introduction of a general fee system for SVHCs** for several reasons (see below). E.g. it would represent a continuous tax on the safe use of SVHCs, where there is no alternative, and where the use may even be essential to society.

List of alternatives: ASMoR **opposes the introduction of a list of alternatives** for several reasons. Our main concern is that there is not always an alternative and rarely ever only "one" alternative for the use of "a" substance. The analysis needs to be **use-specific** and a list of alternatives for a substance would both be oversimplified and misleading. In addition, there are **economic considerations** for the alternative(s) which could not be reflected in the list either;

B. Policy Option 1: Keep the authorisation process, with clarifications and simplifications

ASMoR Members believe that the proposals made in the CARACAL paper would **not render the authorisation process more workable and streamlined**. In Section F we share our views on how the authorisation system could be reformed in a manner that would address the issues it faced in the past.

Importantly, we propose a **relevancy assessment**, which would help target authorisation at uses of SVHCs, where authorisation could truly make a difference (e.g. where a sustainable alternative can be implemented in the near to mid term). We believe that the ECHA Member State Committee could play a role in this relevancy assessment.

C. Policy Option 2: Merge the authorisation and restriction processes

ASMoR has a number of detailed suggestions of what should be considered when possibly **merging the authorisation and restriction processes** (see Section F below). To highlight a few key points:

The proportionate regulatory risk management option should not be determined purely on the basis of hazard. ASMoR supports an **early screening process / ARN / Risk Management Option Analysis** (RMOA) for determining the appropriate way forward. We **object to the proposed broadening of the GRA to also cover industrial uses** (as seemingly considered in the CARACAL paper). We submit arguments, why chemicals risk management in most professional uses are comparable to those of industrial uses and should therefore not be treated like consumer uses.

We commend the Commission for including a paragraph in the CARACAL paper, which acknowledges that not only essential uses, but also **safe uses should be able to benefit from generic derogations**.

D. Role of other legislation and exemptions from REACH Risk Management Options

We appeal to the Commission to reflect further on a **better integration of REACH with other EU legislation**, which provides options for chemicals risk management. Where this other legislation offers the most proportionate way to manage a chemical risk, such an option should be chosen after the screening procedure / ARN / RMOA and the relevant uses of the substance should be exempt from duplicative REACH Risk Management Options.

II. Detailed Comments and Suggestions

E. Comments on the Proposed Reform of the Candidate List

Revising the role of the Candidate List (CL)DU notifications: The proposal put forward by the Commission in the CARACAL paper envisages broadening the scope of the Candidate List (CL) to be horizontally applicable to the three options they proposed in the framework of the Authorisation & Restriction reform. The CL would in the future serve additional purposes aimed at getting more information on uses and exposures of the concerned substances. Broadening the scope of this list by introducing, among others, the **DU notification obligations** on specific uses and exposure/emissions will raise the following concerns:

- It will **multiply the communication obligations** in the downstream supply chains in a non-proportionate way and duplicate the purpose of the ARN section in PACT;
- It will **multiply the SCIP notification obligations**, unless a distinction is made between the SVHC aimed at Art. 9 of the Waste Framework Directive (WFD) and those substances to be listed on the new CL;
- It will be **almost impossible to ensure that all uses and exposures would be known** and, consequently, covered. This is because many DUs are SMEs and have neither sufficient resources and data nor the necessary knowledge about REACH to fulfil such an extended communication scheme.
- It will lead to **wrong conclusions** because supply chains often are global and the manufacturing processes often vary depending on the respective region. It is therefore unlikely that use information can be limited only to the European businesses.

By adding **more administrative burden**, the above concerns will have huge **negative consequences for DUs**, while there is no evidence that it will benefit human health and the environment. In conclusion, we believe that further Downstream User information should be triggered only in **a targeted and time-limited fashion**, i.e. when authorities and industry need the information to screen for the need of regulatory risk management measures. Rather than triggering the obligations by means of a list, which gathers substances on the basis of their classification, other tools could be used to trigger such provision of information (e.g. a data-gathering exercise linked to an entry the ARN section in PACT). Where the need for provision of DU information is identified, this could become part of a regulatory risk management option (e.g. a restriction).

CL as tool to prioritise substances: In the same document, we read that ''*the Candidate List could remain as a tool to prioritise substances for regulatory action, in particular for restrictions but could also contribute to prioritisation for other regulatory action, e.g., under Occupational Safety and Health legislation (OSH), Industrial Emissions Directive 2010/75/EU (IED).*''

On the role of the Candidate List, ASMoR members would suggest using upgraded existing tools or new tools which could help improve supply chain communication while **avoiding an unnecessary duplication of tasks.** Applying this principle already in a very early stage of the process could result in a "*Waiting List of substances for which at a later stage we could take regulatory action*''. Again, the possible role the **ARN section of PACT** rather than of the Candidate List comes to mind. This would also help from an international perspective. The Candidate List is globally known as a black-list. If the Commission is now seeking to establish a list of substances to be assessed and potentially risk-managed, then these substances should not be stigmatised by being included on the Candidate List.

ASMoR would welcome **communication of potential regulatory concerns by authorities early in the process** and if a screening assessment / ARN / RMOA was consistently carried out at an earlier stage. Such an approach would further motivate the industry, which uses relevant substances, to start gathering information needed by authorities already during the screening / ARN / RMOA. Furthermore, where appropriate, industry could start **searching for substitute substances or techniques sooner** and this would support the industry in preparing changes of their portfolio, while also providing **transparency and predictability** to regulatory processes. Such an approach would not only result in more reliable data but would also help to speed up the overall process and thus supports one of the major targets of the Chemicals Strategy for Sustainability.

Proposed fee system for use of SVHCs: With reference to the Candidate list – the future role, it is stated that ''*Fees could be envisaged linked to these notifications to cover resources needed in ECHA and to incentivise substitution*''. To this end, it is proposed that downstream users (DUs) pay an annual "fee" when using SVHCs in the Candidate List. The Authorities' goal is to incentivize substitution, discourage the use of SVHCs and support ECHA to develop information on alternatives for SVHCs.

ASMoR does not agree with the introduction of the ''fee'' under the Candidate List for the following reasons:

1. There are **safe uses of substances in the Candidate List**, some being crucial to support the Commissions´ overall **Green Deal** objectives. Setting a fee in order to discourage the use of SVHCs, without a confirmation on whether the use of the substance is safe, would induce **unnecessary costs and even trigger regrettable substitutions** and obstacles to reach other policy objectives.

2. It is also well known that some substances falling under the definition of SVHCs do **not have effective substitutes** and the introduction of a ''fee'' would then create a sort of **''tax'' for some value chains** with consequent market distortion instead of favoring a level playing field.

3. A fee could be **detrimental to the substitution** of hazardous substances, as companies (e.g. SMEs) may be obliged to **divert R&D funds to pay ECHA fees**. It would be of greater help to fund more R&D programs on substitution. DUs, especially if they are not the registrants of the SVHCs, should rather be incentivised to provide useful information. Industry can provide experienced specialists and run development programs to develop SVHC substitutes, either alone or in partnership with suppliers and other innovators. These programs are often financed by companies themselves and not by public incentives. **More public funds available** for this purpose would also serve as an incentive for DUs to provide useful information for substitution.

4. Some SVHC uses are assessed through **other regulations** (medical devices, FCM…), implementing a fee for such uses is not consistent with the authorization scope as currently implemented."

List of alternatives

In addition, ASMoR Members have concerns regarding the introduction of a list of alternatives, which could serve as substitutes for substances on the Candidate List. Such a **list could only be non-exhaustive and company- and use- specific.** After all, the **analysis of alternatives** (AoAs) cannot be done for a substance as such. Another substance may be suitable to replace the substance in a certain use, but not be suitable for replacing any other use of the substance. [2] Consequently, the described alternatives would often not be representative for a whole sector, but only describe a very specific use. In addition to that, before such a list could be considered as a basis for concrete regulatory actions, the data on reported alternatives would need to be properly verified. Furthermore, the notification-scheme would need to be protected from **targeted abuse** like for example the reporting of incorrect data on alternatives with the objective of harming competitors. In this context, the idea of **using reliable Non-animal methods to screen substances** should be considered beyond grouping of similar substances, but also to start comparing potential alternatives (especially the more data-poor ones) before deciding on their actual plausibility to enable a "safer" use.

Considering these challenges, ASMoR believes that the proposed approach of a list of alternatives would not work in practice. We would also like to stress than beyond ECHA**, other initiatives** of the European Commission (HORIZON Europe, INCITE…) **already offer the adequate structure** to research on chemical alternatives for DUs, for which DUs' resources and support are also required. Creating a **parallel mechanism in the CL would not result in a faster substitution**, even were substitution to be feasible.

F. Comments on the Overall Reform of Risk Management Options

In this Section, ASMoR provides comments on elements of the options as well as on a possible way forward for a reform of Risk Management Options.

1. Option 1 – "Keeping the authorisation process, with clarifications and simplifications"

ASMoR supports the idea that, if today's **Authorisation regime** is meant to continue playing a role, it would **need to become simpler and more streamlined.** As the inception impact assessment found, "*[t]he authorisation procedure is too heavy and inflexible*". Instead of making proposals for rendering the authorisation process more flexible, the **CARACAL paper makes suggestions that would make it even more mechanistic than it is today.** E.g., the paper proposes to move substances more smoothly using a hazard-based approach from the Candidate List to the inclusions of a substance on Annex XIV. In this manner, the highly work-intensive authorisation process would be fed with even more cases, without any mechanism of targeting it at those cases where it could truly make a difference.

In the background paper for the workshop on the reform of the REACH Authorisation and Restriction System, the Commission found that *[f]ollowing the experience with chromium(VI) substances, no other SVHC with a similar widespread use has been recently added to Annex XIV*. Keeping this precedent in mind, rather than rendering the (Candidate and) Annex XIV listing process mechanistic, an idea from the SVHC Roadmap could be picked up, i.e. to **select only 'relevant' substances**. Such a relevancy assessment could be reviewed by the ECHA Member State Committee. To enable the use of

[2] Such AoAs are a very difficult exercise, especially for highly complex products. This is because AoAs can include amongst other important criteria the physical testing of products. A systematic assessment of all listed alternatives per Candidate List substance in order to conclude on its technical feasibility therefore is an unrealistic expectation on industry.

authorisation also for substances with widespread uses, it would be worth considering creating the **option of including only specific uses of substances** (e.g. those where there is a substitution potential in the near to mid-term future) within the authorisation scheme.

ASMoR Members believe that the proposals made in the CARACAL paper for the phase of Applications for Authorisation would only lead to minor simplifications, which by themselves would not make the difference between a functional and a non-functional authorisation system.

Certain proposals would even exacerbate certain problems of the current process: lengthening the deadline given to the Commission for issuing its draft decision from 3 months to 6 months would prolongate a process marred by an already inacceptable length. Rather, for the sake of legal certainty and proportionate administration, an **overall maximum duration for the whole process should be set**, with an **automatic granting** of the authorisation in cases when it does not conclude timely.

Increasing fees with subsequent review report is **unfair and a poor way** to address the suspicion that the applicant may not be trying hard enough to substitute. If that would be the case, the Commission should reflect this, after analysing the specific case, by granting short-lived authorisations, or stronger conditions like reporting on substitution activities. Increasing the fees is unfairly hitting those companies that genuinely cannot substitute due to their particular use or lengthy part and process approval procedures.

2. Option 2: "Merge the authorisation and restriction processes"

As too many aspects remain to be clarified, ASMoR does not have a view as such on the proposal to merge the authorisation and restriction processes. In this subsection, we take the opportunity to comment on underlying principles of the elements proposed in Option 2:

a) Role of hazard for determining the regulatory route

Sections 3.3.1 and 3.3.2 of the CARACAL paper seem to suggest that hazard classification determines the regulatory route:

- Art. 68(2) – **General bans** (GRA), with exemptions only within the framework of the Essential Use Concept (EUC):
  - **Consumer and professional uses** of substances with a classification that would permit them to be identified as **Most Harmful Chemicals** (MHC)
  - Consumer, professional **and industrial uses** of substances with a classification that permits them to be identified **as SVHC**.
- Art. 68(1) – Restrictions, for which authorities bear the burden of proof for demonstrating an unacceptable risk. **Derogations** could be foreseen, for which authorities would bear the burden of proof, too. Industry could also apply for such derogations.

Such a **hazard-based approach** towards choosing the regulatory risk management path would be **highly mechanistic**. It would not sufficiently consider exposure and actual risk, and limit the likelihood for other regulatory Risk Management Options (RMOs) outside of REACH (see also Section G below) to be taken into account. It would fail to learn from experience, i.e. that SVHCs are not in all cases most effectively regulated by focussing on hazard and REACH processes. It would also undermine the work done in the past years, where authorities have assessed substances and their uses and either found that there is no need for further risk management or have already put in place proportionate and sufficient risk management measures.

It should also be noted that basing the assessment solely on hazard will inevitably mean accepting **unintended socio-economic and political consequences**, as the impact cannot be understood in advance. This means the costs in certain situations will far outweigh the benefits, and it may not be possible to remediate the consequences. This could apply, for example, to increased CO2 emissions, lack of EU competitiveness, holding back innovation, and so on.

b) Burden of proof and derogations

ASMoR suggests that it should be considered whether **Art. 68(1) could be revised** in a way that would simplify the process, by **sharing the work better between authorities and industry**. This could be achieved by creating a screening procedure that accounts for information provided by industry at an early stage, i.e. before a specific regulatory route is decided upon. Authorities would then have an option of targeting risk management to where risks occur or where concerns have not been addressed. This would be preferable to avoiding the current workload of Art. 68(1) by choosing GRA-based Art. 68(2) restrictions as a default for all consumer and professional uses of MHCs and consumer, professional and industrial uses of SVHCs.

Such an **early screening and scoping procedure** could also help lighten the workload that might otherwise arise if all derogations had to be fully assessed in a complex process, that would in many respects resemble the current authorisation system and is likely to become unmanageable for industry and authorities (in this respect, please note our position paper on regulatory efficiency, which is available here).

c) Inconsistencies in the CARACAL paper with regard to Art. 68(2) restrictions

In many parts of the CARACAL paper, it reads as if derogations from Art. 68(2) restrictions were only to be granted for essential uses. ASMoR, however, notes that in one paragraph, a major concern of our alliance is being addressed: "*If there are indications that certain uses in articles can be considered 'safe [Footnote explaining the term 'safe use']' during the life cycle of the articles, this could in principle be taken into account in risk management measures, in particular for articles. The impact assessment will evaluate costs and benefits of integrating the horizontal essential use concept in REACH and, on this basis assess how the essential use concept could be combined with the concept of safe use*".

ASMoR commends the Commission for exploring the possibilities of **derogations for essential and safe uses.** It recommends that the 'screening procedure' suggested by ASMoR above be used as an opportunity to properly scope the proposed risk management measure including **relevant upfront exemptions or derogations**, which would limit the need for authorities to assess (possibly very granular) derogation applications from restrictions after these have been decided with a generic or all-encompassing scope.

d) On the remaining lack of flexibility

This point is actually transversal to the three options presented in the CARACAL paper.

The Commission failed to address the lack of flexibility of the current Authorisation system. There is no mechanism to ensure continuity of use similar to a pre-Latest Application Date despite untimely decisions for cases like: development of a new use, new applicants previously covered by an upstream authorisation and seeking their own authorisation, changes in footprint of industrial companies (for example when activities are transferred from one site to another one) and changes in supply chains.

The **Latest Request Date** proposed in Option 2 repeats the mistake of **not taking proper consideration on the dynamic nature of business and industry.** It does not take into account that new uses of an SVHC

may be developed in order to bring innovative solutions to society's needs. The present Authorisation process is looking backwards only, and the revised one should correct this by providing (i) **legal certainty of continued use** during the decision process, followed by a transition period, and (ii) an **emergency procedure** to ensure the necessary agility of European businesses, allowing **fast track authorisation/restriction derogation requests**.

e) On the need to treat industrial and most professional uses differently from consumer uses of MHCs

In its background paper to the Workshop on the reform of the REACH authorisation and restriction system, the Commission states that "*professional users are often using the same products as consumers, but much more frequently and during longer periods of time. Yet, they are unlikely to benefit from the same risk management as in industrial settings. Hence, they should get a level of protection at least at the level of consumers*". This statement is not backed by further evidence, like for example if proportionally a higher number of accidents occur during professional or industrial uses.

ASMoR agrees that risk management in an industrial setting guarantees higher standards and safety for industrial users than could be the case for any usual consumer use. Consequently, **industrial uses should be treated differently than consumer uses.** However, at the same time ASMoR would like to highlight that **risk management for professional uses usually follows higher standards than that for consumer uses** and is often comparable to risk management for industrial uses in matters of safely using chemicals. In this regard we disagree with the general view in the Commission´s background document that implies that currently risks from professional uses are equivalent to those which could arise with consumer uses.

Professional users are usually – just like industrial users – **covered by requirements of the OSH-legislation**, the Seveso directive etc. However, it is a fact that in some Member States there is a gap for self-employed professional users in relation to OSH-requirements. ASMoR is of the opinion that this could be an example, where REACH-restrictions could be used to close such a gap, if this is not possible for the concerned member states within their OSH-framework. Professional users are regularly well-trained professionals who have enjoyed an extensive training on their profession (e.g. carpenter, mechanic, lab technician) and the safe use of the materials – including chemicals – they use. Professional uses are often found in the service-sector and some include the use of highly critical chemicals.

Concluding, ASMoR believes that if there is evidence that certain professional uses need to be similarly protective like consumers uses, such uses and the related risk(s) should be clearly defined and addressed by adequate risk management measures. **Just like industrial uses, professional uses should not be automatically subjected to GRA**. Choosing the **appropriate risk management measure(s)** for these uses, should happen on a **case-by-case basis** and should continue to take into account **socio-economic considerations.**

G. Comments on the Role of Other legislation (raised by the CARACAL Paper as element of Option 3)

As already noted above, the same risk management option (whether this is Authorisation, Restriction, or measures outside of REACH) will not be equally effective in addressing regulatory concerns for all SVHCs or even for all uses of the same SVHC. The Commission's paper for CARACAL notes that "*the Candidate List could remain as a tool to prioritise substances for regulatory action, in particular for restrictions but could also contribute to prioritisation for other regulatory action, e.g., under Occupational Safety and Health legislation (OSH), Industrial Emissions Directive 2010/75/EU (IED)*". We agree that **SVHC listing should be decoupled from the Authorisation Chapter** of REACH (in practice, the

Commission has already applied this approach for SVHCs where Authorisation would not have been the most effective RMO). Inclusion in Annex XIV, or indeed a restriction based on GRA, are not necessarily the most appropriate risk management options for all SVHCs, particularly in cases where uses are primarily industrial (including intermediate uses). Once new substances are included in the Candidate List or prioritised for regulatory action (e.g. in PACT), ECHA could be tasked to conduct a screening / an ARN / an RMOA to determine the most appropriate regulatory pathway to address potential risks. This would allow for a more comprehensive assessment of the interface between risk management measures under REACH and other legislation, such as OSH.

A separate issue regarding the interface with other EU legislation is linked to the paper's proposal to remove exemptions from Authorisation under Article 58(2) (i.e. where any risks are properly controlled on the basis of existing EU legislation). We do not see why it would be beneficial to remove such exemptions, if uses are proven to be safe based on existing regulatory measures. In this regard, ASMoR supports the Commission's proposal in the paper to simplify the process to exempt or derogate "*cases where the risk is likely to be more controlled*" (e.g. uses under strictly controlled conditions or in closed systems where exposure is controlled over the course of the lifecycle; substances where risks are already addressed under OSH, IED, or other legislation such as RoHS, Ecodesign).

ANNEX: List of Members of the ASMoR

1. ACEA – European Automobile Manufacturers' Association
2. AmCham EU
3. BeST
4. Cerame-Unie – The European Ceramic Industry Association
5. CETS – European Committee for Surface Treatment
6. Cobalt Institute
7. ECGA – European Carbon and Graphite Association
8. EFCC
9. EGMF
10. ETRMA
11. Eurobat
12. European Steel Association (EUROFER)
13. Eurogypsum
14. Euromines
15. EXCA
16. FEC
17. FEICA
18. FEPA
19. Flexible Packaging Europe
20. Fluoropolymers Product Group
21. Glass Alliance Europe
22. ICDA
23. IFRA
24. ILA
25. IMA-Europe
26. the Lead REACH Consortium
27. Nickel Institute
28. Orgalim
29. PVthin
30. RECHARGE
31. SME United
32. UNIFE
33. WSM – German Steel and Metal Processing Industry Association
34. WVMetalle