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43. Meeting of Competent Authorities for REACH and CLP (CARACAL) – follow-up – written comments – Agenda item 3.1

DE CA comment on document CA/03/2022 - Discussion on potential options for amendments of the REACH Regulation in order to reform REACH authorisation and restriction processes

The following (technical) comments are suggestions of the DE CA that are intended to enrich the discussion on the design of the impact assessments of the Commission. The comments do not represent a position of the Federal Government.

We thank the Commission for the opportunity to provide further ideas regarding the impact assessment.

The following additional objectives may also be considered:

- Improve data availability and accessibility through extended notification and information requirements for registrants and downstream users, triggered by harmonised CLP classification (CMR, PBT/vPvB, PMT/vPvM, ED)
- Ensure a level-playing field with non-EU companies
- Improve policy coherence (e.g. with waste, plant-related and OSH legislation)

As all projects in the frame of the REACH and CLP-Review depend on each other, the DE CA found it difficult to examine the different options in their entirety. This especially concerns the missing details regarding the Generic Approach for Risk Management (GRA) and the essential use concept (EUC). We understand that they have to be developed in parallel as they also depend on the detailed procedure that will be in place for the authorisation and restriction procedures and vice versa. It seems therefore challenging, to perform a meaningful impact assessment (IA), before first providing a clear and detailed picture of how these two concepts will be implemented.

Nevertheless, in the opinion of the DE CA, the following aspect is missing in the document and should be added to the considerations in the frame of the impact assessment:

If implemented and depending on which of the options presented here will be chosen in the end, there will be two or three paths for regulating uses under REACH:

1.) Authorisation, with the burden of characterising risk and socio-economic analysis (SEA) on the registrants;

2.) Restriction according to Art. 68 (1) with the burden of characterising risk and SEA on the MSCAs and ECHA under the Commission´s mandate;

3.) Restriction according to Art. 68 (2) in combination with Generic Approach for Risk Management (GRA), with no formal obligation to perform a risk characterisation or SEA, while foreseeing, at the same time, far-reaching automatisms for restricting all SVHC consumer/professional uses, unless considered “essential” for society and when no suitable alternatives are available.

The first two pathways mark traditional, science-based risk assessment approaches, while the third can be applied to regulate substances/uses on the basis that a definite set of dangerous substances are assumed to pose an unacceptable risk per se and without the formal requirement of risk-benefit analysis. Using this third approach as a preferred and common pathway - in line with the Council Conclusion[1´]s explicit support of the extension of the GRA -would put much more emphasis on the generic approach. Therefore, the resulting impact requires broad as well as in-depth examination, in fact much more than the first two paths. This should be extensively discussed within the Impact Assessment (IA), not only separately within the IA of the GRA.

As a general point to be considered in this respect: Regulating substances only on the basis of their hazards and essentiality for the society / missing alternatives could result in restricting uses, especially in articles, where there is no risk. Especially articles that contain hazardous substances do not automatically pose a risk. While for CMR substances as such or in mixtures (as in REACH Annex XVII, entries 28-30), the generic assumption of a risk for consumers upon exposure can be considered plausible in principle, the situation is fundamentally different for substances in articles (SiA), where consumer use of these articles may or may not result in relevant exposure.

For the DE CA, it is of utmost importance that there will be enough room to regulate substances, mixtures and articles using the best available option. Therefore, it would be meaningful to have a kind of toolbox of different regulatory procedures and measures. In this respect, we support considerations of combining various elements (`building blocks`) of options 1 and 2. However, elements on the interaction with other legislations from option 3 should also be considered. Also to achieve this, all options and ideas available should be put forward into the impact assessment. We are therefore hesitant to remove one of the options in advance from the impact assessment, maybe due to lacking support in the respective discussion.

As a general aspect to be included in the impact assessment, a kind of scrutiny needs to be considered before initiating each further step within the complete regulatory process. The RMOA considerations are a tool to identify the most appropriate risk management measure, which could be included in the considerations. The IA may assess if and under which conditions a RMOA could be beneficial.

[1] https://www.consilium.europa.eu/media/48827/st06941-en21.pdf

Although different options for the modification of the existing system are presented and individually explained, an overall picture of what was achieved with the REACH procedures so far and what are the current expectations/targets is still missing. As consequence, no overall goal for the reform of REACH authorisation and restriction system is defined against which the expected results of the proposed measures could be evaluated. To rectify the identified deficiencies, a patchwork of individual measures will not be sufficient. Instead, a group of complementary measures will be needed. Therefore, the IA should look for an overall picture and respective targets use this as reference point for the later evaluation of effectiveness and efficiency of the individual elements.

It should also be noted that independently of the option selected it should not be a prerequisite for regulation that the respective substances are included in the Candidate List as there are also urgent regulatory needs for non-SVHC substances and this might unnecessarily delay further regulatory measures.

3.1 Candidate list – the future role

- *Do you agree with the above list of issues that could be integrated? Are there other elements than those identified above that should be taken into account in defining potential new obligations linked to inclusion into the Candidate List to provide further information on use, exposure/emission patterns and alternatives/ substitution activities?*

The described function of the candidate list as a tool for prioritising substances for regulatory action, not only for authorisation, should be discussed. For us, it is important that the adequacy of the possible regulatory measures is evaluated thoroughly, so that the best regulatory action is brought forward. In the current system, conflicts seem to arise from the limited possibilities to deal with the current role of the Candidate List: Regardless of the best identified risk management option (RMO) for a specific substance, all substances on the Candidate List not yet included in Annex XIV have to be considered in the prioritisation exercise. This has already led to situations where substances have been proposed for inclusion into Annex XIV by ECHA, for which there are good reasons not to do so. In some cases, the Commission has subsequently decided not to include the substances in Annex XIV. However, this is only very late in the process and by then a lot of effort has already been invested in processing such substances. Even though we acknowledge that the authorisation process does not only aim at substitution but also serves to better control risks, in such cases, a different RMO (e.g. tailored restriction imposing additional risk management measures for specific uses) might have been more appropriate.

Generally speaking, the introduction of automatisms into regulatory processes always bears the risk of unnecessarily limiting regulatory flexibility. In this regard, automatically linking CLP Annex VI entries to (extended) information requirements seems unproblematic, but the impact of automatically triggering certain regulatory measures on this basis should be carefully evaluated before implementing, in order to be still able to fine-tune regulatory measures on a case-by-case basis.

The DE CA agrees that a procedure to identify substances of an equivalent level of concern (ELoC) as SVHC is needed to ensure that future concerns arising from scientific progress and new knowledge can be addressed.

In the discussion whether the MSC opinion should be removed it should be considered that the MSC is already now only involved if there are critical comments. If MSC would not be involved, these issues would need to be discussed before the substances are proceeded further.

The DE CA generally supports the idea of improving information on uses. From our experience, this can only be achieved by integrating DU into the information duties. The proposed notification system is worth considering. Such information duties should be triggered by harmonised CLP classification (CMR, PBT/vPvB, PMT/vPvM, ED) and for other substances based on SHVC identification.
In our view, such notifications should be clearly defined in the regulation, including use descriptions at the level of the product sub-categories and article sub-categories in REACH guidance R12. Nevertheless, the notification system should not be a substitute for registration requirements as it is stated on the top of page 7. Skipping the registration requirements would make a thorough screening exercise and the ARN (assessment of regulatory needs) approach impossible. Anyhow, new requirements might be burdensome especially for SMEs. They need to be supported in this task.

As an additional element, information on essential uses could be asked for. However, this requires more clarity on the EUC.

The consultation procedures e.g. the Call for Evidence can provide useful information not only from DU but also from other actors (e.g. the Member State authorities) who have valuable information.

Another element that should be considered in the impact assessment is the indirect impact of candidate listing on substitution under the different options. The present candidate list is a basis for lists of avoidable or declarable substances that different industry sectors use in their global supply chain communication.

Elements concerning substance identity to be included in the impact assessment

The inclusion of a substance in the candidate list implies further regulatory processes, such as authorisation or restriction as possible follow up actions. Therefore, the substance definition is an issue, which should be clarified not only in the framework of the candidate list, but also in light of these subsequent regulatory processes.
The issue to be clarified is whether a regulatory provision is addressing a real substance as manufactured (with main constituents and impurities) or an ideal substance as a theoretical 100% pure substance. (This ideal substance can also be addressed as a constituent (main constituent or impurity) of a real substance.)

Consequently, one might discuss to only include ideal substances without information on purity and impurities in the candidate list, especially as the very high concern properties effectively apply only to these ideal substances. Otherwise, it would be possible to include real substances in the candidate list due to an impurity of very high concern, while the main constituent is not of concern. If ideal SVHCs would be identified, further regulations might address the real substances, mixtures or articles containing the ideal SVHCs as constituents.

Furthermore, from a practical point of view, for example, the analysis of an article in the context of Article 33 obligations might also address only ideal substances in the sense of constituents. The Article 33 obligation to provide information is triggered from a content of more than 0.1% of such an ideal SVHC in the article. At this point, it is no longer possible to distinguish if a SVHC was added to the article on its own or by using a real substance containing the substance of concern as an impurity.
The same differentiated consideration of the substance definition is important in the context of the authorisation obligation of substances. The intention of REACH is the safe use of substances and the separation of critical substances from the material cycle. Clarification is needed on the authorisation requirement for a substance, i.e. whether the Annex XIV substance is present as the main constituent or as an impurity in a real substance.

Currently, on the basis on the real substance definition, an Annex XIV substance (ideal substance), which is present as an impurity in a real substance, does not lead to an authorisation requirement for this real substance. Thus, it should be clarified whether the use of the substance on its own (ideal substance) and the use of any substance containing an Annex XIV substance requires authorisation.

Examples:
An Annex XIV substance is present as a constituent in substance **A** in a concentration below 20% w/w. Constituents below 20% are considered as impurities according to the Guidance for identification and naming of substances under REACH and CLP. Currently, there is no need for authorisation of substance **A**, because the SID guidance states that a substance is only defined by the main constituent of at least 80%, which is not included in Annex XIV in this example. However, a mixture, to which the same Annex XIV substance was added above 0.1%, would be subject to authorisation. From the point of view of risk, this situation does not make sense.

Regarding Annex XVII, this situation was already addressed and even solved in several entries, providing explicitly that substances may not be placed on the market or used:

- as substances,
- as components of other substances, or
- in mixtures.

3.2. Policy Option 1: Keep the authorisation (with clarifications and simplifications) and restriction processes

3.2.1. Prioritisation and inclusion of substances into Annex XIV

> *Do you agree with the above list of changes that could be integrated into this option? Are there other elements than those identified above that should be taken into account?*

It should be better explained why it should be favourable to remove the Article 58(2) provision. Furthermore, it should be discussed to add a provision allowing (a derogation of) uses, where a substitution is nearly impossible.

To establish a transparent system, ECHA has developed a so-called scoring approach in order to rank the substances from the Candidate List and prioritise those that should be included into Annex XIV at first place. Although Article 58(3) does not prevent ECHA from also taking into account other aspects than those explicitly mentioned in this Article, only grouping/substitution aspects have been considered in addition so far. The proposed amendment concerning substitution covers these additional elements. This will reduce cases of regrettable substitution as observed over the last years.

Nevertheless, further considerations should be taken into account in the frame of Annex XIV prioritisation as they are of additional relevance with regard to the total impact of an authorisation.

The following additional aspects could be considered in a flexible manner to refine the prioritisation exercise that is based on Article 58(3):

The following aspects might be proposed for deprioritisation:

- Probable impacts of inclusion in the authorisation list on the level of protection
    - Worker protection: Specific EU-wide work place legislation or a specific restriction under REACH may also be suitable instruments to ensure a high level of protection or are already successfully implemented.
    - Consumer protection: For CMR substances restrictions seem to be the more suitable option as supply to the general public of CMR substances and mixtures is banned (via Annex XVII entries 28-30) and for CMRs in imported articles authorisation does not apply.
    - Protection of the environment: PBT and vPvB substances are explicitly mentioned in the REACH Regulation as substances, which should be included in Annex XIV with high priority. In many cases, subsequent restriction would be the preferred risk management measure over authorisation due to the possibility to address intermediate uses, precursors, presence of substances of concern in other substances, imported articles etc.. In other cases, no additional measures are considered necessary because emissions are already well controlled.

- The potential of a substance to be included into the POP Regulation
- Potential impact on (future/key) technologies or essential uses and alternative technologies
- Administrative burden for authorities and industry
    - Number of (different) uses of the substance and number of businesses affected
- Other regulations considered as better options or already in place
- Potential negative effects on recycling

The following (exemplary) additional criteria might support prioritisation:

- Co-exposure to other similar substances
- Substances that can be used as substitutes for other substances already subject to authorisation requirement (prevention of regrettable substitution)

Nevertheless, when creating a more sophisticated prioritisation scheme, care must be taken not to send out the wrong message, as even for substances deprioritised by such a scheme, the pressure for substitution should be kept high. Further discussion seems warranted regarding the question how in such cases work on alternatives can be incentivised although regulation is not immediately pending.

Would you be in favour of removing MSC opinion from the Annex XIV recommendation process?

Currently, the MSC has the task to scrutinise ECHA in performing the correct scoring exercise, only. If there would be further criteria for prioritisation and/or the selection of the best regulatory management option, the MSC would be a well-prepared expert group to give valuable technical input for an informed decision.

Would you be in favour that in case new requirements linked to the Candidate listing to submit additional information would be introduced, only a simplified consultation is needed during the prioritisation process?

In view of the DE CA, it is important that all kinds of stakeholders will have the opportunity to provide their information. In particular, however, MSCA participation in priority setting is considered crucial (notwithstanding a discussion on how the process could be designed to become more efficient).

3.2.2. Application for Authorisation phase

Do you agree with the above list of issues that could simplify the application process and strengthen incentives for substitution, and that it should be included in option 1? Are there other elements than those identified above?

General remarks

The DE CA appreciates the clarification of the scope of exemptions from the authorisation requirement concerning intermediates and scientific research and development.

It should be discussed to establish simplified procedures or exemptions for certain selected areas of use (e.g. process chemicals, low tonnages), as was already developed in 2015 in the AfA Task Force. This could be achieved, for example, through specific data requirements.
Less burdensome requirements might be based on small quantities and not on SME status. Moreover, SME could use large amounts of critical substances.

An authorisation requirement only for certain uses would also be conceivable and may be included in the impact assessment.

One of the main problems of the authorisation system so far is the lack of information on uses. If the information provided in the applications for authorisations concerning the question “What is done with a substance?” is not sufficient, further discussions on alternatives or risk management

measures are not possible. This is independent of the question whether an application is an upstream application or not. The argument that a more detailed discussion of single uses might be impossible for the reason of effort cannot be supported. A clear understanding of uses and risks is indispensable for the later decision-making. The reform of the authorisation system shall ensure that in future sufficient information will be provided for all uses subject to an authorization. In case a possibility for collective derogations for uses independent from specific companies would be implemented, also such discussions could only take place in case a clear picture of uses and risks would be available.

Procedure

The DE CA agrees that the authorisation process needs streamlining so that it would be less burdensome for industry and authorities and more effective.

Data requirements should be phrased more clearly and structured in a better way (e.g. for clearly defining the scope of uses and to draw a line between different uses; representativeness to be achieved in upstream applications). A separate annex with data requirements for authorisation might be favourable here. In the view of the DE CA, it is not sufficient to only revise the guidance.

3.2.3. Evaluation of applications for authorisation and opinion making

Do you agree with the integration of a formal completeness/conformity check procedure and a Forum advice on the enforceability into option 1 and are there particular elements that should be taken into account in defining this element of option 1?

The FORUM check on enforceability should be intensified and not only focus on the conditions proposed by RAC but also on the risk management measures and operational conditions described in the application (currently in the chemical safety report). In the past, sometimes authorisation conditions were vague, and difficult or even impossible to enforce.

In addition, there seems to be the need to improve the cooperation between REACH and OSH inspectors by joint inspections, establishment of processes for exchange of information, and providing clear guidance for shared and divided duties in enforcement.

In order to achieve equal treatment of applications for the same substance the following proposal could be considered: Applications could be collected up to the Latest Application Date. Subsequently, similar uses could be grouped and a decision could be made on all applications grouped in this way at once and on time (before Sunset Date). For this purpose, there would be the possibility of creating a master document and showing the deviations of the individual applications.

Anyhow, experiences from upstream AfAs have shown that the uses are often very generic and that the specific substitution solutions are not applicable for these generic uses. It must be ensured that, for the sake of efficiency gaining, too generic AfAs are not accepted. Otherwise alternatives are rejected because they are not applicable to the broad use. That can reduce the substitution efforts compared to the current situation.

A higher weighting of societal benefits as well as costs could be considered within the framework of the SEA. For essential uses subject to further clarification of how these will be specified), a qualitative description instead of monetarisation would be possible.

3.2.6.1 Restriction process under REACH Art. 68(1)

Regarding the “normal” restriction procedure described in Article 68(1) of the REACH Regulation the DE CA does not concur with the Commission’s assessment that here only minor adaptations would be sufficient.

The development of a restriction via Article 68(1) should remain an additional option to regulate all substances for which it is appropriate for MSCA’s also in the future. With a view to recent experiences with the PFHxA restriction proposal, but also taking into account that in the future more restriction proposals with broad scopes covering large groups of substances are to be expected, the DE CA urges the Commission to also consider amendments of the restriction procedure referred to in Article 68(1) (and described in more detail in Articles 69 to 73) during the upcoming REACH review and its respective IA.

In particular, consideration needs to be given to adaptations of the timelines for the opinion making process. Currently, the 6 months consultation of interested parties takes place in parallel to the 9 months foreseen for the discussion in RAC (and the 12 months in SEAC). It is a well-known issue that this can lead to difficulties for the Committees and similarly for the dossier submitter in case substantial comments (e.g. comments affecting the scope of a restriction) are only submitted towards the end of the consultation period. The time to properly assess and evaluate such comments is too short for all actors. Different options how to improve the process at this stage should be discussed and compared, e.g. the consultation period could be shortened, the Committees could be given more time (e.g. 12 months for RAC and 15 months for SEAC) or start their work only later in the overall process (e.g. after 3 months of the consultation period). An option for RAC to postpone submission of its opinion if substantial comments would be received late in the consultation could be introduced (similar to Article 71(3), allowing SEAC to postpone its opinion making). In general, the review should enable more flexibility of timelines in restriction procedures. Further options could be possible and they certainly all may have their advantages and disadvantages, which need to be assessed.

3.2.6.2. Restriction process under REACH Art. 68(2)

The following remarks shall not be understood as general objections against the generic approach according to Art. 68(2). Nevertheless, in our view these aspects should also be considered within the impact assessment:

We would like to point out that a generic approach for professional uses without a risk based approach needs to consider that professional uses are not always high-risk activities. Professional uses can also be performed by highly specialised, well-trained workers applying adequate risk reduction measures leading to low risks. From the perspective of protection for workers, the appropriateness is doubted to replace the risk based by a generic approach for restriction of professional uses. The precautionary principle seems to be justified only in few cases for OSH.

The distinction between professional and industrial uses is still not clear-cut. A clear definition in REACH is needed. The number of existing professional uses is enormous. A high number of these uses can probably be claimed to be relevant for the functioning of the society. The number of commonly accepted uses that are not necessary is from our point of view very low. That would mean that the decisive question is if there exist adequate alternatives and if the exposure and emissions from these uses are minimised to a level as low as possible. The burden of proof should remain within the industry, not with the authorities.

The inclusion of PMT and vPvM substances in such an approach should be considered. It is specifically the persistency of PMT/vPvM substances, causing the concern for an irreversible and increasing presence in the environment. Continuous presence in water results in continuous exposure of humans and the environment. In order to ensure a more consistent protection of man and the natural environment, PMT/vPvM substances for which a risk can be demonstrated should in principle be eligible for the extended generic approach to risk management as well.

Incentives for a harmonised classification for immunotoxicity have been postponed and should be agreed on the GHS level first. Immunotoxicity resulting in manifest adverse effects is already covered by STOT (RE). On the other hand, the current standard data requirements have limitations to identify immunotoxicants e.g. substances with marked (functional and/or morphological) immunosuppressive effects. Thus, it is too early to discuss an extension to immunotoxicity.

Whether STOT substances present a level of risk comparable to that of CMR substances should be discussed; at least further definition would be needed of which such cases would be in the scope of the generic approach.

It is also noted that some of the effects planned to be added for the Art. 68(2) procedure such as STOT RE and certain ED effects require medium- to long-term exposure.

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

Do you agree with the general description of measures for defining Option 2 or are there other elements that need to be clarified? Do you have any other suggestions than those explained above?

As a general remark: The comments made before concerning the candidate list, restriction and authorisation processes should also be considered under Option 2.

The DE CA sees a challenge for the transition process of merging the two systems. Specification of the process for phasing in ongoing activities/dossiers should be included.

Another goal of this option should be the introduction of a level playing field with non-EU companies as the authorisation-like application for derogations could also be necessary for imported articles. This could be an element for the IA.

From the document and the CARACAL discussion it is understood that COM proposes that substances included in the candidate list will be prioritised for the Article 68(2) procedure by COM involving the MS. Within the prioritisation exercise, other options have to be considered, e.g. also measures outside REACH. We wonder how the technical discussion on the best regulatory action

would be implemented. In our view, it is essential that the impact of all possible options is considered thoroughly.

Within this proposal, the DE CA would strongly suggest to discuss the option of preparing Article 68(1) restrictions also for SVHC substances. The arguments posed by COM are not convincing (transfer of Annex XIV to Annex XVII and burden of proof should not be reverted to the MS) as also now MSCA's are preparing Article 68(1) restrictions for SVHC substances.

The role of the MSCA in this Option 2 seems to be reduced to just discussing the priority for the Article 68(2) procedure. When using only this procedure for SVHC substances, a high burden due to the high number of substances would be placed on COM. We fear that this would overload the tasks of COM and it would significantly hamper the regulation of critical substances. In this respect, the DE CA would strongly suggest that the MSCA remain the main actors in the restriction work (preparation of restriction proposals/dossiers). One option in this respect is that also MSCA could prepare Article 68(2) proposals.

Moreover, the DE CA is concerned about the additional workload which results from skipping scientific discussions in ECHA Committees for all SVHC for consumer and professional uses within the restriction procedure and mandating the REACH Committee to develop an opinion on the derogations. In addition, the practicalities as well as legal legitimisation of this Committee deciding about the essentiality or dispensability of sometimes hundreds or even thousands of different consumer products containing the substance(s) under consideration need further discussion. At any rate, significant additional resources would be necessary for this Committee to examine also the restriction proposals.

In addition, it should be evaluated in the IA how much additional resources would be needed in the Commission services to process Article 68(2) proposals within an appropriate time-frame and without the "guidance" from ECHA's Committees. It should be noted here that since the entry into force of REACH the Commission only processed very few Article 68(2) restrictions.

Another aspect should be considered in the impact assessment: We need innovation in safe and sustainable chemicals to achieve the goals of the green deal and transformation of economy and society, while at the same time maintaining a high level of protection of human health and the environment. Therefore, the impact assessment should clarify how derogations from restrictions could address these trade-offs. The impact of prohibiting the production and use of the most hazardous substances on the basis of the precautionary principle against the use of safe and sustainable chemicals for other sustainability goals by substituting substances of concern and phasing out the most harmful chemicals for non-essential societal uses should also be considered. This concerns the use of substances which can be properly controlled and which are needed for the transformation of economy and society strived to in the Green Deal. Aspects concerning decreasing resources and circular economy could be included. Anyhow, substitution of the most hazardous substances is the overarching goal.

A more ambitious merging of the two procedures, such as applying both procedures for a substance in such a manner that it fits best for the specific uses should also be considered. This may be achieved, for example by integrating the authorisation aspects also into the restriction procedure following Article 68(1).

A further key element would be clear requirements in the regulation for the information that would have to be provided in the applications for derogation, and especially for the granularity of the use descriptions (see general comments).

The sound justification of the derogations will be critical in view of possible legal challenges. Clear descriptions (and distinctions) of all derogated uses in Annex XVII may be difficult to achieve because their first scoping relies on the applicants. It should also be indicated whether applications for derogations by industry are permitted and if so, for what areas. The rejection of out-of-scope-applications could be considered. The possibilities to appeal for rejected derogations should be considered as well as the review process for time-limited derogations.

It is assumed that in option 2 all uses not identified as essential will be restricted. This could mean all articles on which no derogation has been requested would be banned. Obviously, the actors expected to request derogations (former applicants) are not the same as those who could ask for derogations on articles (DUs, importers). If interested parties are not informed and well prepared at time, no request for derogations will be submitted. A respective mechanism should be considered.

As pointed out in the document, the joint applications may bring about the same issues previously encountered with the upstream applications. We suggest further clarifying how these issues may be dealt with. Experiences from upstream AfAs have shown that the uses are often characterised very generically and that the specific substitution solutions are not applicable for these generic uses. It must be ensured that the implementation of „generally applicable (joint) derogations requested by industry“ does not lead to the application of very generic upstream derogations. This can reduce the substitution efforts compared to the current situation.

To limit the number of individual applications for derogations, incentives for joint applications should be discussed (e.g. longer periods until phase-out, exchange forums).

Enforceability is also a matter of GRA, and FORUM could be considered for involvement also here.

Within the impact assessment, the necessary resources for the Commission, ECHA and the Member States, as well as the possibly far-reaching consequences on the consumer product market should be considered. Furthermore, it should be further assessed, how to deal with groups of substances.

3.4. Policy Option 3: Remove the authorisation title from REACH partially

- Do you agree with the general description of parameters for defining Option 3 or are there other elements that need to be clarified? Do you have any other suggestions than those explained above?

For consumer health and for the health of the general population, neither the OSH Regulation nor Actions under the Industrial Emissions Directive would compensate the loss of regulatory flexibility associated with this option. Therefore, Option 3 is regarded as a step back in consumer health protection.

In spite of the COM’s intention to extend the GRA/EUC concepts, the document does not contain

any discussion of the interplay with and implications for other legislative sectors with relevance to consumers, e.g. cosmetics, toys, product safety under the GPSD, but also pesticides/biocides (for consumer use), food contact materials etc. Some of these sectors currently apply their own risk-benefit analyses and it is therefore recommended to discuss the consequences of the proposals made in the present document on a larger scale, in particular with respect to the OSOA principle.

A better linking with the IED should also be considered for options 1 and 2. See also proposals from the HAZBREF project: Finnish Environment Institute > Hazardous industrial chemicals in the IED BREFs (HAZBREF) (syke.fi)

- Do you agree that if all uses of the most hazardous substances in consumer and professional uses can be restricted in accordance with Article 68(2), industrial uses could be regulated nationally under workers' safety legislation and industrial emissions legislation (with the possibility to impose EU restrictions in accordance with Article 68(1), if harmonisation is needed)?

An overarching aspect, which needs to be considered for improvement of authorisation and restriction procedures, is the harmonisation with other legal areas, such as regulations for occupational safety and health. Therefore, a more in-depth discussion concerning the interface of REACH and OSH including the WPC would be welcomed, e.g. how the hierarchy of measures (STOP principle) should be implemented into REACH, and conflict of REACH and OSH with nationally implemented occupational exposure limit values (OELV).

In the view of the DE CA, authorisation is a good instrument to support OSH. It is recognised that in the authorisation process, the information on use conditions, exposure and especially adequate risk reduction measures has increased and there are indications that this, together with the authorisation conditions, has improved working conditions. Furthermore, an increased ambition to fulfil substitution duties already implemented in OSH legislation is observed.

Precautionary principle und risks based regulation for the protection target worker

The DE CA would like to point out that regulatory measures following the precautionary principle should be different concerning different protection aims. Definition in the EU: 'The precautionary principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.' (Communication from the Commission on the precautionary principle, European Commission, COM (2000) 1). In OSH legislation the duty to comply a risk assessment, not to exceed limit values and to apply risk reduction measures is implemented. The OSH legislation is meant to deal with chemicals on purpose but under properly controlled conditions. The uncertainties and data gaps are more limited compared the consumer or environment.

- What are CARACAL members views on possibility to retain Candidate List and to use it as a tool to prioritise substances for regulatory actions under REACH and non-REACH processes.

The DE CA appreciates the proposal to investigate the possibility to use the Candidate List as a tool for prioritisation for all regulatory actions. Nevertheless, as stated above, the inclusion into the Candidate List should not be a prerequisite for regulation.

Further considerations:

Innovation and how to support substitution, improving enforceability and impact especially on SMEs

It should be investigated, how independent research and development, description of best practice of successful substitution and circulation of these solutions as well as support for the implementation of changes in industry could be provided. One option could be to set up an independent entity with experts in the field of alternatives assessment.