Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction

Annexes

[Written by VVA, RPA (Europe, Okopit, Logika and Imen)]
[February – 2023]
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction

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1. Annex 1: Report on Task 2 – Use maps

1.1. Aim and objectives

The purpose of Task 2 was to provide a mapping of the uses that will be concerned by the extension of the Generic Risk management Approach (GRA). In Task 2 the registration information was analysed for substances that have proven or assumed hazardous properties that may, depending on the later design of the REACH Regulation, qualify them to be regulated via the GRA.

The analysis forms the basis for further impact assessment and further work in Task 3 in evaluating different implementation scenarios. Specifically, the following information was provided:

1. Mapping of the main product types that are potentially affected by an extension of the GRA and estimate the number of substances likely to enter those product compositions. These can be considered as high-level “proxies” for the number of sectors potentially affected and as an indication of how much they might be affected.
2. Getting an idea of the market significance of the substances identified by providing additional tonnage information.

1.2. Approach and Method

The starting point for the work in Task 2 was a list of substances (in the following referred to as Master List of Substances – MLoS), which was compiled by ECHA on a cross-project basis and whose aim was to determine how many substances with certain classifications are available in their database. This substance list included not only substances with known harmonised or self-classifications, but also a forecast of how many substances might still be classified over time.

The list was generated by ECHA based on registration data. Here, it should first be made transparent which substances with potential properties were included in the analysis and how the substances were selected that formed the basis for the use mapping. The list includes registered substances that may fall into one (or more) of the hazard categories that could be covered by the application of the generic approach to risk management (GRA). For an overview of the hazard categories see Table 2.

The MLoS consists of three Baskets. According to an accompanying ECHA document, the Baskets 1 and 2 have the following characteristics:

- “Basket 1 – Substances with confirmed hazard(s): For endpoints\(^1\) included in CLP, these are based on either their harmonised classification (inclusion in Annex VI to CLP) or the reported self-classification in the registration dossier\(^2\). For other endpoints, these are based on identification as SVHCs (inclusion in the Candidate List), identification under the Biocidal Products Regulation (BPR) or agreed in the

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\(^1\) ECHA (2021) Issue 1.2 Report (restricted)

\(^2\) The descriptions are taken 1:1 from the ECHA 1.2 report, which uses the term “endpoints” here. In the following, we will use the term hazard classes for the sake of simplicity, as this seems more generally understandable. This is done in the knowledge that not all properties are currently covered by a legally defined “hazard class” in the sense of the CLP Regulation. For PBT and ED substances, such hazard classes are the subject of the parallel revision of the CLP Regulation, which was not yet completed at the time of this report.

\(^3\) Certain entries on Annex VI to CLP are conditional (e.g., the classification only applies if certain impurities are present). These have been removed from the analysis. In addition, self-classification can be impacted by the presence of impurities. In this analysis, no attempt has been made to identify and remove substances if the self-classification is based on impurities.
ED/PBT Expert Groups. Hazard(s) are based on available information; lists as well as numbers of substances are provided.

- **Basket 2 – Substances where the hazard(s) are under consideration**: These are substances with on-going data generation or assessments; lists as well as numbers of substances are provided; it also includes an estimate on the number of substances for which the hazards are likely to be confirmed (based on past experience).[*]

A third Basket is represented by estimates of the number of substances in the chemical universe that may be classified according to the new hazard classes based on the assumption that the same proportion of hazardous substances exists regardless of their manufactured and/or imported quantities (and therefore registered providing different information requirements according to REACH Annex VII, VIII, IX and X). It is important to note that Basket 3 is not a list of identified substances and therefore cannot be used for the purpose of use mapping. However, the estimated numbers composing Basket 3 can be used for the sensitivity analysis of the impact assessment (tasks 3 and 4).

The initial list did not cover substances classified as carcinogenic, mutagenic or reprotoxic (CMR) properties. However, this was considered relevant to assess the impacts of the GNA on professional uses, ECHA was asked to compile substances with CMR 1A and 1B properties. These substances are not relevant for the consumer products sector as they are already covered by the scope of the current regulation in Article 68 (2) of REACH.

Compared to the previous request on other hazards, ECHA was not asked to provide ‘estimates’ on the numbers of substances that may ultimately meet the CMR cat 1 criteria but was asked to retrieve the list of substances with current indications of such hazards (known/confirmed CMRs; equivalent to Basket 1 in the previous request). The dataset provided does therefore not include substances with CMR Cat 1 hazard ‘under consideration by authorities’ (i.e. substances with ongoing data generation or assessments; equivalent to Basket 2 in the previous request). Furthermore, no estimate on how many substances could have the same hazard(s) among the remaining REACH registered substances (equivalent to Basket 3 in the previous request) is provided.

An overview of the hazard classes and the selection criteria applied is given in the following Table 1.

---

### Table 1: Hazard classes in the scope of the MLoS and selection criteria for the identification of substances

<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Selection criteria Basket 1 – Known hazard</th>
<th>Selection criteria Basket 2 – Hazard under consideration</th>
</tr>
</thead>
</table>
| Specific Target organ toxicity – single exposure (STOT SE) | • substances classified as STOT SE 1 or 2 in Annex VI of CLP  
• substances self-classified in REACH registrations | • Concluded Substance Evaluation (SEv) cases where STOT SE was indicated to be of concern  
• Ongoing or planned SEv cases where STOT SE was indicated to be of concern  
• Concluded Risk Management Option Analysis (RMOA) cases where STOT SE was indicated to be of concern  
• Ongoing CLH proposals where classification for STOT SE has been proposed |
| Specific Target organ toxicity – repeated exposure (STOT RE) | • substances classified as STOT RE 1 or 2 in Annex VI of CLP  
• substances self-classified in REACH registrations | • Concluded Substance Evaluation (SEv) cases where STOT RE was indicated to be of concern  
• Ongoing or planned SEv cases where STOT RE was indicated to be of concern  
• Concluded Risk Management Option Analysis (RMOA) cases where STOT RE was indicated to be of concern  
• Ongoing CLH proposals where classification for STOT RE has been proposed  
• Substances flagged as possible STOT RE in GMTs Assessment of Regulatory Needs (2) |
| Respiratory sensitizers (Resp. Sens) | • Substances with a harmonised classification as Resp Sens in Annex VI of CLP; or  
• Resp Sens self-classifications in REACH registrations | • concluded substance evaluation cases where Resp. Sens. was indicated to be of concern; or  
• ongoing or planned substance evaluation cases where Resp. Sens. was indicated to be of concern; or  
• Concluded Risk Management Option Analysis (RMOA) cases where Resp. Sens. was indicated to be of concern; or  
• Ongoing CLH proposals where Resp. Sens. has been proposed; or  
• Substances flagged as possible Resp. Sens. in Assessment of Regulatory Needs GMTs |

(1) [https://echa.europa.eu/understanding-assessment-regulatory-needs](https://echa.europa.eu/understanding-assessment-regulatory-needs) Group Management Team; expert team set up to establish substance group at ECHA.
<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Selection criteria Basket 1 – Known hazard</th>
<th>Selection criteria Basket 2 – Hazard under consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBT and vPvB</td>
<td>- Substances identified as PBT listed in the Candidate List (PBT (SVHC list); - Substances identified as vPvB listed in the Candidate List (vPvB (SVHC list)); - Substances concluded as PBT and/or vPvB in PBT working list of substances; - Biocides assessed as PBT (Conclusion for PBT and/or vPvB (BPR PBT assessment list): PBT; - Biocides assessed as vPvB (Conclusion for PBT and/or vPvB (BPR PBT assessment list): vPvB</td>
<td>- Substances on PBTEG(^2) working list with assessment ongoing or inconclusive; - Substances included in the CORAP with concern for PBT/vPvB; - Substances under ongoing Substance Evaluation with concern for PBT/vPvB; - Concluded (positive) or unresolved Substance Evaluation (SEv) cases where PBT/vPvB was indicated to be of concern; - Concluded (positive) Risk Management Option Analysis (RMOA) cases where PBT/vPvB was indicated to be of concern; - Substances flagged as possible PBT/vPvB in Assessment of Regulatory Need</td>
</tr>
<tr>
<td>PMT/vPvM</td>
<td>- Substances identified as persistent, mobile and toxic listed in the Candidate List as having Equivalent Level of Concern (EloC) according to REACH Article 57 (f) were included in the Basket 1.</td>
<td>- Substances flagged as possible PMT/vPvM in Assessment of Regulatory Need; - Substances listed in the report by DTU(^3) (Potential PMT and/or vPvM)(OK)</td>
</tr>
</tbody>
</table>

\(^2\) PBT expert group.
\(^3\) How many potential vPvM/PMT substances have been registered under REACH? – vPvM/PMT -screening by using the DeriSAR database Hofberg, et al. (2021)
<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Selection criteria Basket 1 – Known hazard</th>
<th>Selection criteria Basket 2 – Hazard under consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrine Disruptors - human health (HH)</td>
<td>• Substances identified as ED HH listed in the Candidate List (ED HH cat 1 (SVHC list)).&lt;br&gt;• Substances concluded as ED HH in EDEG working list of substances (Concluded ED HH)&lt;br&gt;• Biocides assessed as ED HH (Conclusion for ED (BPR ED assessment list): ED HH)</td>
<td>• Substances on ED Expert Group working list with assessment ongoing or inconclusive&lt;br&gt;• Substances included in the CORAP with concern for ED&lt;br&gt;• Substances under ongoing Substance Evaluation with concern for ED&lt;br&gt;• Concluded (positive) or unresolved Substances Evaluation (SEV) cases where ED was indicated to be of concern&lt;br&gt;• Concluded (positive) Risk Management Option Analysis (RMOA) cases where ED was indicated to be of concern&lt;br&gt;• Substances flagged as possible EDs in Assessment of Regulatory Need&lt;br&gt;• Substances where a EOGRTS has been requested with/without F2 triggered based on ED concerns&lt;br&gt;For biocide and pesticide active substances COM should consider the JRC impact Assessment for the ED Criteria. In particular, Option 3 of this impact Assessment sets out the number of substances likely to meet the criteria for confirmed or suspected EDs.</td>
</tr>
<tr>
<td>Endocrine Disruptors - environment (ENV)</td>
<td>• Substances identified as ED ENV listed in the Candidate List (ED ENV cat 1 (SVHC list)).&lt;br&gt;• Substances concluded as ED ENV in EDEG working list of substances (Concluded ED ENV (ED assessment))&lt;br&gt;• Biocides assessed as ED ENV (Conclusion for ED (BPR ED assessment list): ED ENV)</td>
<td></td>
</tr>
<tr>
<td>CMR 1A 1B</td>
<td>• there is an active or inactive registration that contains at least one GHS classification record that classifies the substance as CMR 1A or 1B, or</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard class</td>
<td>Selection criteria Basket 1 – Known hazard</td>
<td>Selection criteria Basket 2 – Hazard under consideration</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>• there is a harmonised classification in Annex VI of CLP for Carc. 1A or 1B (excluding the ones for which any of the notes(^6) J, K, M, N, P, O, R, 8 applies), or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• there is a harmonised classification in Annex VI of CLP for Mut. 1A or 1B (excluding the ones for which any of the notes J, K, P, 9 applies) or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• there is a harmonised classification in Annex VI of CLP for Repr. 1A or 1B</td>
<td></td>
</tr>
<tr>
<td>Notes:</td>
<td>• self-classification information has been extracted only from lead and individual registrants; substances for which the only CMR 1A/1B classification is present in member dossiers are not included in the analysis, but such classifications can be considered as “conditional” given that there is a divergence of classifications in the joint submission</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• conditional harmonised classifications, as identified by the corresponding notes, have been excluded</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• harmonised classification has been taken from the 14th of CLP</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• self-classifications have been extracted on 9 Feb 2022</td>
<td></td>
</tr>
</tbody>
</table>

Based on this approach, the MLoS contained the following number of substances as shown in Table 2.

\(^6\) These notes refer to Annex VI CLP section 1.1.3. "Notes assigned to an entry"
<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Number of substances Basket 1 – Known hazard</th>
<th>Additional Info</th>
<th>Number of substances Basket 2 – Hazard under consideration</th>
<th>Additional Info</th>
</tr>
</thead>
</table>
| Specific Target organ toxicity – single exposure (STOT SE)                  | 187                                           | 20 CLH          | 23                                                          | • 21 may be confirmed\(^5\) (91%)  
|                                                                             |                                               |                 |                                                             | • Basket 3\(^5\): It is estimated that there are 418 substances warranting classification as STOT SE 1 or 2, including the 197 already identified. |  
| Specific Target organ toxicity – repeated exposure (STOT RE)                | 1,711                                         | 393 CLH         | 71                                                          | • 40 may be confirmed (56%)  
|                                                                             |                                               |                 |                                                             | • Basket 3: It is estimated that there are 4270 substances warranting classification as STOT RE 1 or 2, including the 1711 already identified. |  
| Respiratory sensitisers (Resp. Sens)                                       | 408                                           | 91 CLH          | 71                                                          | • 54 may be confirmed (78%)  
|                                                                             |                                               |                 |                                                             | • Basket 3: It is estimated that there are 935 substances warranting classification as Resp Sens, including the 468 already identified |  
| PBT and vPvB (combined)                                                     | 27                                            | 7 only biocidal active substances  
|                                                                             |                                               | 5 PBT only registered biocidal active substance  
|                                                                             |                                               | 2 vPvB only registered biocidal active substance  
|                                                                             |                                               | 27 relevant for REACH  
|                                                                             |                                               | All substances on Candidate List or concluded by PBT/vPvB expert group       | 324                                                          | • 77 may be confirmed (24%)  
|                                                                             |                                               |                 |                                                             | • Basket 3: It is estimated that there are about 396 substances which may be identified as PBT/vPvB, provided that the data was available. |  
| FBT                                                                         | 23                                            | NA              |                                                             |  
| vPvB                                                                        | 28                                            | NA              |                                                             |  

\(^5\) Estimate by ECHA  
\(^6\) Estimate by ECHA
<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Number of substances Basket 1 Known hazard</th>
<th>Additional Info</th>
<th>Number of substances Basket 2 Hazard under consideration</th>
<th>Additional Info</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMT/PvM</td>
<td>9</td>
<td>• Several also included to REACH annex XIV or POP regulation</td>
<td></td>
<td>• 89 may be confirmed (25%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Number of PBT/PvB substances on Candidate List higher (108) but several</td>
<td></td>
<td>• Basket 3: Based on additional conditions an estimate would lead to a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>without REACH registration thus not included</td>
<td></td>
<td>range of 70 - 403 substances which may be identified as PMT/PvM,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>provided that the data was available.</td>
</tr>
<tr>
<td>Endocrine Disruptors Substances</td>
<td>24</td>
<td>• All Candidate List substances (Article 57 (f))</td>
<td>434</td>
<td>• 140 may be confirmed (32%)</td>
</tr>
<tr>
<td>(combined HH/ENV)</td>
<td></td>
<td>• 2 ED HH only registered biocidal active substance</td>
<td></td>
<td>• no differentiation HH ENV</td>
</tr>
<tr>
<td>human health (HH)</td>
<td>13</td>
<td></td>
<td></td>
<td>• Basket 3: It is estimated that about 1012 substances may be identified</td>
</tr>
<tr>
<td>environment (ENV)</td>
<td>19</td>
<td></td>
<td></td>
<td>as ED HH/ENV, provided that the data was available.</td>
</tr>
<tr>
<td>CMR 1A and 1B</td>
<td>1,124</td>
<td>• In total this analysis identified approximately 1500 substances but not all</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>were registered</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1) There are a total of 21 (3+11) substances registered at Annex X (in Basket 1 and estimated to be confirmed in Basket 2). It is estimated that about 231 substances may be identified as PMT/PvM, provided that the data was available. Estimates provided by the available reports (USA Texte 126/2016 p. 54-55, https://www.umweltbundesamt.de/publikationen/reach-improvement-of-guidance-methods-for-thair)

- Arp, H.P.H., Hae, S.E., 2019; 1.0 - 1.7% of the REACH registered substances
- DTU report; 6.3 - 1.7% of the 2073 substances
- Hot Target approach: 0.9% of the substances assessed
<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Number of substances Basket 1 Known hazard</th>
<th>Additional Info</th>
<th>Number of substances Basket 2 Hazard under consideration</th>
<th>Additional Info</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Assumed reasons:
- Tonnage below 1 ton per year
- “legacy” substances not placed on the market anymore
- Substances classified but not in the scope of REACH registration as substances that are unintentionally produced in processes (e.g. polycyclic aromatic hydrocarbons (PAH) etc.)
The initial list consisted of 3,654 individual entries. After the addition of additional CMR 1A and 1B substances, the number of entries increased to 4,778. Note, however, that the same substance may appear under several hazard categories. This may be relevant when considering different regulatory options and assessing the impacts but may be of secondary importance for use mapping purposes. To avoid impacts being included more than once, the duplications were determined by comparing the sub-lists for the individual hazard classes.

According to the CSS, PMT/vPM substances are not specified as hazard classes that should be subject to the extended GRA and were, therefore, not included in the scope of the study according to the ToR. Still, after discussions in the scoping phase of the study, they were included in the assessment to understand the potential impacts of regulation in this emerging hazard class and its thematic proximity to the subject area under investigation.

1.2.1. Initial Information Request to ECHA

For the substances identified by ECHA on the MLoS, a query was performed on the information 'use description' coming from registration dossiers. These were submitted to the research team in the form of EXCEL extracts from REACH IT as so-called ‘use data matrices’. Such a use data matrix was submitted individually for each hazard class. Table 2.3 and Figure 1 below show the number of substances identified under each basket for each hazard class, as well as the number of substances for which use description information from registration dossiers has been provided by ECHA.

The delta between the two figures can be explained by the fact that not all substances identified in the MLoS are registered. Furthermore, a limited number of registered substances do not include any use information. Use description information has been retrieved from both active and inactive registrations.

Therefore, the number of use data matrices received was lower than the number of substances on the initial list. An overview of the numbers on the initial list, the use information and the relative distribution of the use information between the hazard classes can be found in Figure 1. In total, 4,500 data sets were provided in the various hazard classes. Since a substance may be assigned to more than one hazard class and basket, by adjusting for this effect, the data sets represent individual 3,358 substances that were the subject of further analyses.

---

<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Number of substances Basket 1 – Known hazard</th>
<th>Number of substances Use maps received per hazard class</th>
<th>Number of substances Basket 2 – Hazard under consideration</th>
<th>Number of substances Use maps received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Target organ toxicity – single exposure (STOT SE)</td>
<td>197</td>
<td>184</td>
<td>23</td>
<td>25</td>
</tr>
<tr>
<td>Specific Target organ toxicity – repeated exposure (STOT RE)</td>
<td>1,711</td>
<td>1,554</td>
<td>71</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory sensitisers (Resp. Sens)</td>
<td>408</td>
<td>397</td>
<td>71</td>
<td>66</td>
</tr>
<tr>
<td>PBT and vPvB (combined)</td>
<td>27</td>
<td>20</td>
<td>324</td>
<td>300</td>
</tr>
<tr>
<td>PBT</td>
<td>23</td>
<td>12</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>vPvB</td>
<td>28</td>
<td>19</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>PMT/vPvM</td>
<td>9</td>
<td>7</td>
<td>355</td>
<td>318</td>
</tr>
<tr>
<td>Endocrine Disruptors Substances (combined HH/ENV)</td>
<td>24</td>
<td>21</td>
<td>434</td>
<td>422</td>
</tr>
<tr>
<td>human health (HH)</td>
<td>13</td>
<td>10</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>environment (ENV)</td>
<td>19</td>
<td>17</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>CMR 1A and 1B</td>
<td>1,490</td>
<td>1,124</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

19 NA: not applicable for PST/vPvB and ED. ECHA has not made any further differentiation between PST and vPvB and ENV and HH in the MLoS. For CMR, no prediction of future substances was made, as these were only collected during the ongoing work. There is therefore no data for Basket 2 (and also not for Basket 3, which is only a prognosis without specific substances and thus lacking any use information).
Figure 1: The figure shows the distribution of substances in the MLoS according to hazard classes for Basket 1 (green) and 2 (pink). In each case, a column is shown next to the column for the initial number, which represents the number of use maps obtained. The pie charts show the relative distribution of the use maps between the hazard classes.
1.2.2. Use mapping

The use data matrices were subject to further processing to prepare the use mapping. Use information was extracted from the use data matrices. The life cycle descriptions from the registration dossiers served as a basis. The following information was analysed:

- Product Categories (PC) according to the systematic provided via the use descriptor system: This information was used to determine the number of substances that could be used in a given application area.

- Life cycle stages, in particular, uses by consumers and professionals as provided by registrants via their life cycle description in the registration dossier. Furthermore, uses were identified that involved service life as a subsequent step. This also includes service life, which follows industrial use, which means that articles resulting from industrial use of a substance may also be subject to the GRA if they are themselves used by consumers or professional users.

The subsequent impact assessment (Task 3) uses the number of substances in the individual PCs and the respective life cycle stages as the first input variable. For a further level of consideration, the total registered tonnage band of substances possibly covered by the GRA was extracted from the public ECHA database and assigned to the substances. The total registered tonnage band might be a relatively weak indicator of the market significance, but since there is a lack of more use-specific tonnage information or of other indicators that would describe the significance of the use of a substance at a general level, this is the only further approximation currently available for the extent of impacts.

Based on the initial data input by ECHA, several use structuring approaches were generated to serve as input data for the impact assessment. The data structure is based on the analysis model used in the actual impact assessment (see Task 3). The structured data (use maps) were compiled in EXCEL sheets that allow data analysis. The structure of these EXCEL sheets is shown in Appendix I of this report.

The following settlements were also made for the use mapping:

The MLsOs contains both cat. 1 and cat. 2 substances in the area of STOT SE and RE substances. Cat. 2 substances, analogous to CMR substances, should not be the subject of a future GRA. It was therefore not considered further in the use mapping. STOT RE and SE is only represented by cat 1. This distinction was not made in Basket 2, as there was no information on this. Thus, of the original 725 STOT RE substances (out of the original 1711 substances included in the MLsOs for STOT RE), only 217 are STOT cat 1 and relevant for the GRA. The remaining 507 substances are contained in professional or consumer products according to the registration data, but are cat 2 and are therefore not processed further for the impact assessment.

PMT substances are not under consideration to be included in the GRA. However, they are included in the use mapping as far as possible to be able to consider the effects of a possible future regulation within the framework of the sensitivity analysis of the impact assessment. They are also presented in the following sections in order to give an impression of the main areas of use.
2. Annex 2: Consultation strategy

2.1. Objective of the consultation

The consultation for the study aimed to collect both qualitative and quantitative data and information to contribute to the impact assessment of the reform of the REACH regulation. The focus of this consultation was the GRA to further hazard classes and uses, and the REACH authorisation and restriction provisions.

Stakeholders were consulted either to collect evidence or to test/validate pre-existing analysis or evidence. As part of this study, a wide range of stakeholders were consulted, such as EU institutions and agencies, national authorities, industry representatives and their associations as well as NGOs.

2.2. Consultation activities

The consultation activities were manifold and designed to target a wide range of stakeholders through a series of key activities using multiple tools and channels, in order to gather insight from as many relevant views as possible. The consultation activities included:

- Scoping interviews (October 2021)
- Interviews on authorisations and restrictions (4 April to 13 May 2022)
- Interviews on enforcement (mid-June 2022)
- A public consultation (20 January to 15 April 2022)
- A targeted online survey on authorisations and restrictions (1 May to 3 June 2022)
- Workshops (9 and 12 November 2021, 21 March 2022, 27 June 2022)
- An SME panel questionnaire (3 March to 6 May 2022)
- CARACAL meetings with Member States and other stakeholder observers (27 January 2022, 29 March 2022, 6 July 2022)

The table below summarises the number and type of stakeholders consulted in each consultation activity.
<table>
<thead>
<tr>
<th>Stakeholder group</th>
<th>Consultation methods</th>
<th>Workshop(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU institutions or agencies</td>
<td>Scoping interviews</td>
<td>1st workshop: 0</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2nd workshop: 1</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>3rd workshop: 5</td>
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<tr>
<td></td>
<td>2</td>
<td>4th workshop: 0</td>
</tr>
<tr>
<td>Companies and business associations</td>
<td>26</td>
<td>1st workshop: 0</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>2nd workshop: 50</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>3rd workshop: 127</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>4th workshop: 122</td>
</tr>
<tr>
<td>National authorities / agencies</td>
<td>13</td>
<td>1st workshop: 18</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>2nd workshop: 0</td>
</tr>
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<td></td>
<td>41</td>
<td>3rd workshop: 16</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>4th workshop: 27</td>
</tr>
<tr>
<td>NGOs</td>
<td>7</td>
<td>1st workshop: 0</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>2nd workshop: 8</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>3rd workshop: 8</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>4th workshop: 9</td>
</tr>
<tr>
<td>Other stakeholders (consultancies, indivi-</td>
<td>-</td>
<td>1st workshop: 0</td>
</tr>
<tr>
<td>duals, academics, research)</td>
<td>-</td>
<td>2nd workshop: 16</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>3rd workshop: 9</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>4th workshop: 9</td>
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<tr>
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<tr>
<td></td>
<td>89</td>
<td>2nd workshop: 16</td>
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<td></td>
<td>168</td>
<td>4th workshop: 9</td>
</tr>
<tr>
<td></td>
<td>423</td>
<td></td>
</tr>
</tbody>
</table>

With regards to the public consultation, there have been 770 contributions, and approximately 750 uploaded documents.

15 The numbers below include only the "active" participants for each of the four workshops. Many more stakeholders followed the discussions "passively".
16 The European Commission representatives who are part of the workshop’s organisation team were not included in this table.
17 For the first workshop (9 November 2022), the Slovenian Presidency and the European Commission invited only representatives of Member States to take part. The following Member States were represented: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Romania, Spain, and Sweden. In addition, Commission staff, ECHA staff and consultants from VVA participated in the workshop as moderators and rapporteurs for the world café tables.
3. Annex 3: Results from scoping interviews

3.1. Methodology

The purpose of the scoping interviews was to gather as much first-hand experience as possible from the most relevant stakeholder groups. Throughout the month of October 2022, 14 scoping interviews were carried out with EU institutions/agencies, companies and business associations, and NGOs.

The scoping interviews enabled the study team to further define data needs, identify impacts, map stakeholders and develop the methodology of the study further, based on the stakeholders’ experience in the field. The interviews provided the research team with qualitative information on key aspects of the ongoing reform. The interviews were performed in a semi-structured format to encourage an open two-way communication.

In terms of the scope, discussions revolved around the subjects of GRA as well as elements of the REACH authorisation and restriction procedures. The outcome of these interviews supported the fine-tuning of the methodological approach for the impact assessment exercise.

3.2. Results: Extension of GRA

- Representatives of authorities argued that the broadening of GRA would represent a quick and efficient way to tackle the risks of the most hazardous substance. However, some industry representatives raised concerns that this would constitute a major shift from a risk-based approach towards a hazard-based approach. Therefore, some industry representatives argued that GRA should also reflect, to some extent, the level of exposure and usage of substances (e.g., in medical devices, aerospace, automobile). Some of the authorisation and restriction procedures were considered as overly burdensome or disproportionate for very specific industrial processes.

- Representatives of all stakeholder groups pointed out that a greater number of substances in the scope of GRA restrictions would lead to increased administrative burdens, both for public authorities and industry representatives. Concerns were expressed regarding the speed and efficiency of the process in achieving the ultimate objective of the Chemicals Strategy for Sustainability (CSS) of reaching a toxic-free environment by 2050.

- Many stakeholders from all groups questioned the scope of the GRA extension. A successful extension of GRA should be accompanied by a clear definition of its scope and key concepts (consumer vs. professional uses and the definition of the concept of essential use). In addition, the term ‘essential use’ also appears in documents related to the EU Taxonomy which increases the importance of the definition. The scope of the extended GRA should be carefully discussed and focused on the areas where it is most effective, so that it becomes a meaningful tool and serves its purposes.

- In terms of possible environmental and human health impacts, industry stakeholders suggested that it was important to understand the specific properties of substances. This would help leverage the effort to define their exposure limits to achieve real benefits.

- According to some industry and NGO stakeholders, practice has shown that often the properties of substances are used as the only relevant factor, without taking
sufficiently into account that not only those properties, but also the concentrations or types of use of the substance, determine the overall risk.

- From an economic perspective, some industry stakeholders raised concerns regarding lost market opportunities. The impact of GRA on SMEs is unpredictable as it depends on the practicalities of the GRA implementation, as well as on the companies’ size and their portfolios. Smaller companies or those with a less diversified portfolio would find it more difficult to replace substances covered by restrictions under the extended GRA.

- Several industry stakeholders mentioned that it was important to apply and enforce similar requirements on imported articles.

3.3. Results: Authorisations and Restrictions

- Industry and authority stakeholders pointed out that both processes have their advantages and disadvantages. Authorisation and restriction procedures should be perceived as one common system of risk avoidance and risk management. Both authorisation and restriction suffer from lengthy procedures which, in stakeholders’ broad opinion, have not led to appropriate actions in a timely manner.

- Authorities explained that REACH as horizontal legislation has three major roles: (1) to drive substitution, (2) to provide a source of information on uses, exposure and alternatives, (3) to provide support of risk management for critical uses. All of these roles must be considered in the reform.

- Industry stakeholders explained that the impacts are very sector specific. For instance, the medical technology and automobile industries have particularly complex supply chains resulting in lengthy research and development procedures, which lead to the use of a high number of substances in typically very small volumes. The position of the companies in the value chain was also an important driving factor of their attitudes. The views of downstream users and representatives of the chemical industry differed significantly.

- It was pointed out by industry representatives that authorisation is a costly and time-consuming process that requires significant internal company resources. In the view of the medical and automobile industries, authorisation was claimed to be a less suitable tool for risk management than restriction. In addition, the divergence of treatment under REACH for a similar group of products, (i.e., medicinal (pharmaceutical) products and medical technologies), was pointed out.

- When looking at possible other challenges of authorisation, industry stakeholders mentioned that the system penalises EU manufacturers disproportionately compared to importers which can have a detrimental effect on the competitiveness of the EU industry (relocation of production outside the EU).

- Among ways to improve the current authorisation process, most of the stakeholders from industry indicated that data requested during the process from the data holder (i.e., companies) should be better focused and narrowed down to the specific uses. The system should provide more predictability and certainty about the outcome of the process to the industry (this applies also to the restriction procedure, as described below). Moreover, the number of individual applications should be limited and favour a collective application system for similar uses (the application submitted by several companies on the same use).

- Many industry stakeholders pointed out that the authorisations and restrictions are not always rightly used to address identified problems and risks. Therefore, it was
suggested that a better scoping phase would enable more efficient use of both restrictions and authorisations. Some representatives of NGOs also pointed out that restrictions under article 68(1) together with article 68(2) restrictions under the extended GFA could allow the European Commission to leverage the effort to look for alternatives. Among the key challenges of the restriction process, the following were mentioned:

- Lack of proportionality, scoping and/or prioritisation of substances, which may result in disproportionate regulation of some substances (e.g., in covering the use of very small quantities) when compared to the risk to the environment and health;
- Burden of proof on Member States' authorities which may considerably slow down procedures and reduce the scope to a limited number of substances and their uses (where clear information is available);
- Lack of data on uses and exposure;
- Legal uncertainty resulting in difficulties in accessing the market.

- Some representatives of medical devices and in-vitro diagnosis suggested that it would be beneficial if the burden of proof would be shifted from authorities and ECHA to industry. In turn, this would result in restrictions being as targeted as possible from the outset, applying only to those specific uses where there is an identified need, and exempting other uses on the basis of appropriate conditions (e.g., exposure limit values, and appropriate transition periods).

- Representatives from the medical devices and in-vitro diagnosis sectors also suggested, based on the sector's 15 years of experience, to improve the restriction process by defining the scope of proposed restrictions upfront, taking several aspects into account. Under such an approach, existing medical devices and in-vitro diagnostics, with which Europe’s healthcare systems expect to be continually supplied, could be subject to control measures of health and environmental impacts and scrutiny with an emphasis on finding alternative and sustainable substances for new products.

- As a consequence, representatives of medical devices and in-vitro diagnosis considered that more targeted restrictions, i.e., with a more refined scope for specific uses, would present several advantages:
  - Simplicity (as once implemented no additional work would be required);
  - Predictability and legal certainty;
  - Companies could focus on implementation and authorities on enforcement;
  - Support and incentive for innovation in new technologies.

Finally, two industry stakeholders mentioned the importance of the transitional period for regulated substances. Transitional periods were perceived by some stakeholders as a suitable way to identify alternatives, which at the same time could reduce the number of derogations in the long term.

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16 During the scoping interview phase, around 20 representatives of the industry were represented. The scoping interview was performed in the format of a focus group.
4. Annex 4: Results of Interviews

4.1. Methodology

Between 4 April 2022 and 13 May 2022, overall 48 stakeholders’ interviews were carried out with companies and business associations, national authorities, NGOs and consumer organisations. The stakeholders’ interviews aimed to

- refine the study team’s knowledge and understanding from desk research and literature review on the impacts of broadening GRA and different options to revise the REACH authorisation and restrictions,
- identify the optimal characteristics of the different options and to compare them,
- understand key impacts which would be further verified and expanded during the other stakeholder consultation activities (i.e., online survey).

Interviews differed depending on the type of stakeholders addressed. The first round was launched after the desk research and literature review. The second round was carried out after the public consultation. Following the results of the consultation, the interview questionnaires were thus refined.

Three different types of questionnaires were designed for different types of stakeholders:

- industry
- national authorities
- NGOs and trade unions

The interview questionnaires were designed to supplement the technical consultation via the CARACAL meetings on 27 January on authorisation and restriction reform and on 23 March 2022 on the GRA, as well as the public consultation. It also supplemented the 3rd workshop held on 21 March 2022, which focused on obtaining further detail on “use maps” of substances/application that may be affected by the extension of the GRA. The interviewees had the possibility to attach (or refer to) their responses to the CARACAL papers (CA/03/2022 and CA/19/2022) to complement their responses.

4.2. Extension of GRA

4.2.1. Authorisations and Restrictions

General

- NGOs and authorities explained that one advantage would be the improved recycling potential and reduced contamination of material flow. There would be prevention of direct and indirect exposure to consumers. This effect would be more pronounced for endocrine disruptors (EDs). Regarding recycling patterns, the system does not work at the moment. There is uncontrolled recycling and very little was put in place to safeguard from hazardous chemicals. The recycling problems will not be solved by continuing to use the most hazardous chemicals. Some recycled plastic products contain even worse chemicals than virgin plastic. These chemicals need to be banned completely because they add up when the materials are reused.
• NGOs pointed out the reversal of the burden of proof to industry as one of the key advantages of the GRA. New registration requirements on risks and exposure are needed and due to its wider application of restrictions, the process would help to collect that information.

• According to some authority respondents, another advantage of the GRA approach would be that the hazard classes need to be properly defined, which currently is not the case for all hazard classes. A timeline should be established with the goal of having all these hazard classes first classified and then banned in consumer and professional uses by 2030.

• Many industry, NGO and authority stakeholders saw the increased speed of regulation as the key positive impact of an extension of the GRA and highlighted that the procedures need to be developed in a way that can enable this speed.

• One interviewed industry stakeholder could see an imaging advantage from the application of the GRA to plastics, as it would make it easier for the industry to prove the safety of plastics.

**Extension to professional uses**

• NGOs stressed that this would provide better protection for the environment against contamination from professional uses. The GRA should improve recycling and circular economy patterns, and so will improve the situation from the start of the life cycle. Subsequently, the impact at the end of the life cycle after a few years would be very positive. The scope of GRA should be focused on the CSS for both products for consumers and professional uses.

• Several industry stakeholders pointed out the advantage of restrictions over authorisation to ensure a fair competition as they apply to all market participants, which benefit the companies well versed in the regulatory process.

**Extension of the GRA to articles**

• Industry stakeholders discussed that the different requirements for substances, depending on whether they are used in articles or mixtures, are a challenge for regulation and need to be addressed. The different data requirements can pose difficulties when substances are included in articles because the information requirements change in the course of the value chain.

**4.2.2. Arguments critical of an extension of the GRA**

**General**

• Some industry stakeholders see a risk of even longer procedures for GRA restrictions, as the new ones have not been tested and could overwhelm the Commission, if not well designed. This risk was especially seen in respect to the number of derogation procedures or the scope of restrictions.

• Animal welfare NGOs highlighted that including further hazard classes in the scope of GRA restrictions could require additional animal testing and be very detrimental to animal welfare with no significant improvements in environmental protection. As an example, ED tests do not provide results applicable to human situations.

• Many industry and some authority stakeholders perceived the extension of GRA as a move away from a risk-based approach to a hazard-based approach. In their view, the current system provides a good system of risk management. Hence, the GRA
should be only expanded to uses and substances where there is clear evidence that the risks cannot be managed. Some authorities questioned the new hazard-based approach pointing out the link to exposure is very important to focus the regulatory work and burden on the substances with the most risk.

- Many industry stakeholders question the application of the GRA to many areas where safe use has already been demonstrated (especially but not exclusively on professional uses). Using hazard (and not risk) as the key criteria leads, in their view, to creation of many costs without the adequate human health or environmental benefits.

- Furthermore, industry stakeholders stressed that Article 68(2) restrictions cannot take into account specific situations and sectors, due to the general considerations on exposure, while at the same time the current Article 68(1) restriction and the authorisation processes can. For instance with:
  - Medicinal products,
  - Metals and PBTs,
  - Substances affecting the respiratory systems, such as enzymes.

- Industry stakeholders named the following uses and products as potentially affected by an extension of the GRA:

<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Functions or products</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED – HH</td>
<td>Biocides, medicinal products, bleaching agents, protections against infection, wind turbines</td>
</tr>
<tr>
<td>ED – ENV</td>
<td>Biocides, medicinal products, bleaching agents, protections against infection, wind turbines</td>
</tr>
<tr>
<td>PBT</td>
<td>Water chemical repelling, medicinal products, automotive textiles, PPE, technical textiles with high-end applications, distillates, polymers</td>
</tr>
<tr>
<td>vPvB</td>
<td>C6 chemistry(^1), technical textiles, PPE, distillates, water chemical repelling, high resistance against heat under required conditions, durability, long-life ability, medicinal products, automotive textiles, PPE, technical textiles with high-end applications, polymers</td>
</tr>
<tr>
<td>STOT SE</td>
<td>Solvents, acids, smell &amp; taste preservation</td>
</tr>
<tr>
<td>Immunotoxic</td>
<td>Biocides, protection against infection, in-can preserver, allergy prevention, technical textiles in special applications</td>
</tr>
<tr>
<td>Respiratory sensitisers</td>
<td>Enzymes(^2), detergents and cleaning products for consumers and professionals, preservation</td>
</tr>
</tbody>
</table>

**Extension to professional uses**

- Many industry stakeholders see problems with overlap and contradiction between the extension of the GRA and Occupational Safety and Health (OSH) provisions with respect to professional use. It is contradictory in the sense that professional

\(^1\) It should be noted that C6 chemistry is already targeted by the on-going Article 68(1) restriction process for PFNaA, its salts and related substances, for PFAS in fire-fighting foams and by the future Article 68(1) restriction dossier for PFHxS under preparation by the Member States. As such, possible restrictions of C6 chemistry should be seen as part of the baseline and not of the option to extend GRA to additional hazard classes.

\(^2\) Biodegradable proteins which catalyse reactions under moderate conditions with very small amounts. Enzymes replace other chemicals and save pollutants, OSH and energy. Enzymes can also contribute to low-temperature laundry washing and remove, not only visible stains, but also other soils from clothes for well-being and human health.
users are usually trained and do have access to RMM/PPE, and it restricts even uses that are deemed safe according to workplace risk assessment.

4.2.3. Other Comments on the GRA extension

- Authority stakeholders saw the improved prioritisation process focusing on the substances with the highest risk as the key advantage of having more information. An extension of the candidate list would not help as the resources would be not sufficient to deal with all these cases without prioritisation.

- A clear timeline is needed for the implementation of the GRA. In the view of many industry stakeholders, ECHA and the European Commission have been the bottleneck in respect to the regulatory processes like restrictions and authorisations. The timing should depend on the resources of the European Commission and ECHA. The prolongation of the basic process is to be expected especially in relation to the derogation schemes, essential use, minimal exposure etc. The derogations need to be temporary.

- Authority stakeholders highlighted that both Member States and the European Commission should be able to initiate the procedure for GRA restrictions. Therefore, a dossier should also be prepared for GRA restrictions (a reduced annex XV dossier on scope and derogations) which ECHA’s scientific committees should evaluate before the European Commission puts forward a proposal to the Member States. The new legal text should reflect the commitments in the CSS including deadlines. Furthermore, the legal text should reflect criteria for when to apply article 68(2).

- Authority stakeholders pointed out that concentration limits should be established to harvest synergies between REACH and CLP, the GRA limit values. For mixtures and articles, the limit values should be the generic classification limits for mixtures. For articles, the classification limits should apply for homogenous materials. If a substance has a specific classification limit, this should apply. Conditions of use may be introduced to limit the risk of uses derogated from the generic restrictions.

- Industry stakeholders suggested that proteins and enzymes in powder form can act as respiratory sensitisers, and therefore are relevant in relation to GRA. Special attention to proteins, enzymes, and their use on consumer products should be made when considering respiratory sensitisers in relation to GRA. Possible derogations from an automatic ban on detergents and other products should be considered and assessed for these substances.

- Overall, Member State authorities gave positive feedback on the current Article 68(2) restriction process and its efficiency and effectiveness:
  - The process has led to the effective restriction of harmful substances for certain consumer uses. However, this procedure has been applied only a limited number of times and does not cover all CMR Category 1 substances present in consumer products. A positive example of group restrictions can be found in textiles. The process on certain CMR substances in textiles and footwear took much more time than a regular REACH article 68(1) restriction proposal does.
  - The extension should be done in such a way that the process allows for swift and efficient scoping, proposal drafting and decision making. It is of utmost importance to learn from the article 68(2) experiences under the current legal situation and use those experiences to build a solid, efficient, and predictable legal and practically implementable process to use for GRA restrictions or authorisations for the chemicals of highest concern.
4.2.4. Comments on the four reform options on authorisation and restriction

4.2.5. Comments in favour of one of the options

Options 1

- Several industry stakeholders (and some authority stakeholders) pointed out their preference for improving the current system (Option 1) compared to significantly changing the system. Mostly they were arguing that a more profound change as foreseen in Option 2 and 3 would cause too much uncertainty and disruption. A question was raised especially about the future setting of the derogation process in Option 2 and 3.

- Some industry stakeholders were critical of the introduction of fees for substances in the candidate list, arguing that inclusion in the candidate list already provides a strong incentive to substitute a substance, which fees would not increase.

- Some industry stakeholders were also concerned that the notification obligation would be very difficult to enforce. Using the information from DU would be beneficial for manufacturers but it will require the building up of administrative processes and a data collection infrastructure.

Option 2

- Several authority and industry stakeholders voiced that the derogations of general applicability could provide a real advantage in respect to administrative burden and predictability. As an example, the Chromium(VI) case with a high number of applications for authorisation was mentioned.

- NGOs were more critical of Option 2 and 2A. While the idea to use more flexibility for authorisation and restriction is good, these options are not favoured. The prioritisation of a candidate list is unacceptable as it is judged to slow down the regulatory process, which is contradictory to the reform ambition. The idea behind the reforms of Articles 68(1) and 68(2) is to regulate chemicals quickly. NGOs are not convinced that Options 2A and 2B would save resources.

Option 2A

- Some authority stakeholders pointed out that the Annex XIV list in Option 2A could be developed into a "waiting list" to collect information. This could improve the prioritisation process and provide more clarity.

Option 3
Some authority stakeholders believed that Option 3 would allow a better integration of OSH and IED with REACH which would be very useful.

4.2.6. Comments critical of one of the options

Option 1
- No real disadvantages were mentioned by stakeholders.

Option 2
- Some authority stakeholders and industry representatives were not in favour of the loss of importance of the authorisation process.

Option 2A
- Some authority stakeholders were uncertain about Option 2A as it replicates the challenges of the ‘upstream application issue’. This was found to be a major problem with the authorisation process.

4.2.7. Any other comments on the four options

- NGOs commented that in terms of impacts of the proposed reforms on human health and environment, some of the solutions proposed will not improve the current situation or may even worsen it. NGOs also noted that the assessment of the alternatives is a very difficult process. As for SVHCs, there should be obligations to put forward alternatives available to the industry. The options do not suggest how to ensure that the alternative providers are taken into account.
- NGOs found that some of the options are at odds with the CSS. For instance, the minimal exposure should be only used for industrial uses, which is not specified. NGOs are concerned about the enforceability and the role of the Forum. It will add complexity, overburdening the resources of authorities and resulting in a further slowdown of procedures.
- On extending the role of the Forum:
  - Several authorities stated that they were in favour of an extension of the role of the Forum:
    - The enforcement point should be thought through in the restriction and authorisation decisions.
    - The role of the Forum is very important. The impact of an extended role will depend on the resources the Member States can make available. It is time consuming to provide support for the Forum. This might be an issue for smaller Member States
    - The Forum should be involved early on in the decision-making process to ensure that decisions taken consider potential risk management measures and enforcement actions into account. Otherwise this work has to be done twice.
  - On the other hand, authority representatives voiced some concerns about the extension of the role of the Forum:
    - The impression is that until now, the Forum has not delivered a lot of efficient recommendations. Nevertheless, authority representatives
believe the Forum has an important role in coordinating and ensuring the exchange of views and good practices between the Member States and ECHA.

- There is uncertainty as to whether this would help the process. The assessment requires involvement of many different experts. It might be challenging to mobilise all of these experts.
- The functioning of the Forum does not fit a formal role with opinions development as RAC and SEAC. Therefore, it would be preferred if the Forum could have an advisory role.

- Different authority and industry stakeholders pointed to specific existing proposals to improve the assessment process on whether alternative substances are available, either by allowing other parties to provide evidence on existing alternatives or by founding an independent institute for those assessments.
5. Annex 5: Results of targeted online surveys

5.1. Methodology

From 1 May to 3 June, the study team collected the specialist views of different categories of stakeholders through an online survey to gather feedback about the proposed options and their potential impacts (including impact chains). The survey was carried out electronically through a web-based tool. A total of 89 stakeholders provided replies to the survey, which was targeting companies and national authorities. One questionnaire targeted companies specifically, while another was sent to national authorities.

The online survey aimed to verify the robustness of data collected from interviews. It aimed to support the findings with objectively verifiable evidence based on a larger and more representative sample of the population.

To improve the representativeness of the sample, stakeholder mapping was used in the following way:

- Before the start of the survey, the study team verified whether all the identified organisations and types of stakeholders were part of the sample of email addresses. They were then contacted with the survey.
- During the survey, care was taken to review which groups had provided responses and which had not, to guide the sending out of reminders and other activities for take-up.
- At the end of the survey, take-up was assessed among stakeholder groups, to ensure that eventual biases in the analysis of the results were known.

Through this survey, stakeholders provided views on the effectiveness and efficiency of both the current REACH Regulation processes and how this could change (for better or worse) under the policy options presented.

The survey was structured in two main parts, the first part dedicated to the extension of the use of the generic risk management approach and the second part dedicated to the revision of authorisation and restrictions processes.

The feedback from the survey is summarised in the subsections below. It first provides the views gathered on the extension of GRA, and secondly on the reform of authorisation and restriction process. To facilitate the exercise, each of the subsections discusses first common points in favour of each element and subsequently develops on the critical elements that have been emphasised.

5.2. Feedback on the extension of the GRA

5.2.1. Comments in favour of an extension

General

- NGOs commented that the extension of the GRA might lead to a higher level of protection for human health and the environment. In particular, it would improve the protection of vulnerable groups, consumers and professional users by bringing safer products to the market, preventing the exposure (mixtures and articles).
Several industry and authority stakeholders highlighted the advantages of an enforcement of group restrictions linked to CLP classifications, arguing that the restriction process would be simpler and "automatic".

Another advantage mentioned by authority stakeholders was that the extension of GRA should drive the substitution of SVHCs with safer alternative substances or technologies, foster innovation and provide clearer incentives for substitution.

Public authorities expect a reduction of administrative burden on their side as they would not be requested anymore to prove unacceptable risk to ban a hazardous substance. From the public authorities standpoint, this would increase the efficiency of the process.

Industry representatives consider that the extension of the GRA would foster innovation processes, however, only if a clear procedure for prioritisation were to be established including the application of the safe use concept.

Several public authorities' representatives highlighted the benefits of the inclusion of the STOT, Neurotoxic and respiratory substances under the GRA. Although not fatal, their costs for the society in the long run could be significant as they cause long-term and chronic illnesses.

**Inclusion of professional uses**

- NGO stakeholders pointed out that there is a fine line between products used by professionals and those used by consumers. Extension of the GRA to professional uses, among others, could contribute to the 'One Health' approach and the Commission Beating Cancer Action Plan.

- Public authorities' representatives mentioned that REACH restrictions would be adopted via a faster procedure than the currently the OELs under OSH. Hence, objectives would be reached quicker.

- One industry representative highlighted that a more preventive approach under REACH could enhance human health, the environment, and water resource protection.

**Inclusion of articles**

- NGOs thought it to be important that the extension of the GRA covers imported products and articles, which is not the case at present.

- According to public authorities' representatives, the extension of the GRA would avoid the occurrence of the most problematic substances in articles and mixtures (along their life cycle). The importance of this impact depends on the extent to which the GRA would be applied to broad categories of articles.

- According to the public authorities, not allowing SVHCs in any consumer and professional product by default would increase clarity for the market and consumers. Putting a limit on a number of substances in recycling, reuse and circular economy would ensure safety across the supply chain and the limited occurrence of the most problematic substances in articles and mixtures. The significance of this effect will depend on the extent to which the GRA is applied to broad categories of articles.

- NGOs thought that environmental protection at the end of life could be improved if implemented correctly.
5.2.2. Comments unfavourable to an extension of the GRA

General

- Several industry stakeholders pointed out that SMEs would be affected disproportionately by the extension of the GRA compared to others due to:
  - their lower capacity to deal with regulatory issues;
  - limited ability to switch to alternatives;
  - difficulties in accessing resources for substitution.

- Multiple stakeholders (authorities and industry) were concerned by the overlap of the planned REACH revision with other pieces of EU legislation, especially with sectoral legislations (e.g., toys and cosmetics, OSH, IED).

- More than 10 industry representatives raised their concerns about the loss of product functionalities in case of the GRA extension. This manifests in the impact on product acceptance and satisfaction obtained thanks to restricted substances while their alternatives cannot confer the same level of functionality. Moreover, it was highlighted that having a substitute for a substance or mixture does not necessarily imply that there is a substitute for an article. The final product should be evaluated for safety and reliability. This can also lead to a decrease in sustainability, performance and endurance of products.

- Industry stakeholders foresee an important investment to be done on their side allowing to ensure enforcement of the extended GRA. The enforcement could be even more problematic for products for which a significant number of substances would be banned under the extended scope of GRA. This would imply the risk that there is no transfer of compositional data through supply chains contrary to mixtures.

- Many industry stakeholders expect a risk of regrettable substitution (alternatives being less safe, sustainable, or with a lower technical performance) or practices. This could result in loss of important solutions on other EU policy objectives (the EU Green Deal targets).

- Some public authorities' representatives expect that the scientific discussion and the decisions regarding hazard identification and/or classification of substances under the CLP Regulation may be delayed or disrupted because of the possible consequences triggered under the planned REACH reform.

- Public authorities' representatives expect some difficulties to arise from the hazard classes targeted in the CSS in relation to the Most Hazardous Chemicals. Concerning immunotoxicants and neurotoxicants, a suitable definition needs to be developed. There needs to be an assessment of these effects with respect to threshold values and suitable test methods.

- For industry representatives, the extension of GRA could result in potential risks of unavailability of spare parts for older and complex products. The extension of GRA could hinder the production of some spare parts.

- Industry representatives brought attention to the issue of some substances used in small quantities (e.g., in medical devices). According to the industry, these should be considered under different modalities. The application of equal restrictions would create a disproportionate burden.

- Some public authorities' representatives questioned the assumption that all hazard classes are equal as they found that the impacts of some hazard classes (e.g., ED and CRM) are far more serious and require more attention than other hazard classes considered.
Many industry and public authorities’ representatives raised their concerns on the possible rise of environmentally harmful substitutions if the restrictions do not consider the recyclabiity of substances and their replacement.

**Inclusion of professional uses**

- Industry representatives noted that the extension of the GRA is not based on established risk assessment standards, which according to them already provides high safety. There would be a loss of relevant and unique substances or a reformulation of a large number of products due to the hazard-based approach, while their safe use has been demonstrated. More than 4500 substances may be in scope, affecting up to 100% of the product portfolio for some companies without a real advantage for the environment or human health.

- The industry stakeholders pointed out that the extension of the GRA may cause a risk for the environment and human health if the GRA does not distinguish between hazard and risk. GRA-based restrictions would bypass necessary detailed risk assessments of substance-specific exposure, resulting in restricting substances for which safe use is secured. Stakeholders were concerned that the GRA would contradict the precautionary principle by also restricting safe uses.

- Most of the public authorities’ representatives highlighted that it is essential that the notion of “professional uses” would be clearly defined, to avoid restriction of professional uses where the conditions are put in place and adequate training is provided. The distinction is needed when defining the professional and industrial uses. This would include the risk assessment under OSH (as training, use of equipment) and should not be duplicated under REACH.

- Both public authorities and industry representatives highlighted that the extension of GRA could negatively impact the competitiveness of EU industry. This could result in professionals purchasing their products in non-EU countries or an illegal trade of restricted substances.

- Most of the industry representatives highlighted that higher compliance costs would impact companies’ innovation efforts due to reduced availability of substances for formulations. Overall, the industry representatives expect disproportionate economic and societal impacts from the extension of GRA to professional uses (depending on substances applications).

- Several industry and authority stakeholders mentioned the need to accompany the extension of GRA with a sound derogation procedure. The public authorities’ representatives suggested that an automatic system of restrictions based on risk management could produce unintended effects. The final outcome of the extension of GRA could only be assessed when coupled with a number of exemptions and authorisations granted. The timeframe of derogation and its complexity would affect the phasing out time.

**GRA restrictions for substances used in articles**

- The industry representatives raised concerns regarding the enforcement procedure, especially of imported articles:
  - Non-compliance of articles imported from non-EU countries, especially by consumers;
  - An increased risk of unfair competition vis-à-vis non-EU countries.

- Multiple public authorities’ representatives pointed to the need to provide clarification on modalities of application of elements such as limit values, minimal exposure and
essential use concept, which is even more important in articles due to different information requirements and the different abilities of authorities to prove the use of substances.

- Public authorities also explained that the hazard-based approach could be disproportional for articles for which exposure may not be an issue (at least in the use-phase). The prohibition of uses with no release and exposure during the whole life cycle (including waste and recycling) should be eligible for exemption in addition to essential uses.

5.2.3. The reform of authorisation and restriction

5.2.4. Arguments in favour of specific options for reform

Option 1

- Several industry stakeholders pointed out their preference for Option 1, arguing that profound change under Options 2 and 3 would bring too much uncertainty (e.g., a new derogation process).
- Several industry stakeholders reported that they preferred the restriction process compared to the authorisation process due to the better predictability of the process and potentially required substitution processes.
- Many public authority representatives stressed that the burden of proof should be on the industry. They see the lack of information needed for prioritisation as the key obstacle for better and quicker implementation of restrictions.
- According to some public authorities' representatives, the REACH authorisation process should be clearly defined with respect to the requirements for the content of the authorisation application (e.g., "suitable alternative").

Option 2

- Public authorities' representatives suggested that ECHA's Scientific Committees should assess the derogations proposed by the Commission under Article 68(2). It should be possible to incorporate risk management measures into derogations, joint derogations, authorisations and exemptions due to essential use to ensure the safe handling of the substances. The scheme should create fair competition for companies that do not apply for authorisations as they have already substituted the most harmful substances, and for SMEs.

Option 2A

- Several public authority stakeholders saw the following advantages of Option 2A (keeping separate annexes):
  - Stronger legal clarity (survey Public Authorities, Excel row 12), especially in the restrictions for which companies can apply for exemptions (survey Public Authorities, Excel row 13). It would also maintain the legal certainty that is in the current REACH version for the substances included in Annex XIV (survey Public Authorities, Excel row 14).
  - Support for any option that will lower the number of AIs, as the time spent on these applications does not correspond with the achieved health or environmental benefits (survey Public Authorities, Excel row 13).
Several stakeholders highlighted that it would allow for a faster decision-making process, while retaining the positive elements from the current processes and keeping the existing useful procedures (survey Public Authorities, Excel rows 7, 6, 10).

Keeping the SVHCs list, regulating the SHVCs in a similar way, and keeping a ban of substances based only on hazards with clear incentives towards full substitution of SVHC industrial uses (survey Public Authorities, Excel rows 7, 10, 11) were also mentioned. Furthermore, it was highlighted that it would allow other substances to be regulated and allow an interplay between Annex XIV and Annex XVII (survey Public Authorities, Excel rows 10, 11).

5.2.5. Arguments critical of one of the options

Option 1

• No real disadvantages were mentioned by stakeholders.

Option 2

• Industry stakeholders voiced concerns that the process laid out for Option 2 seems long and complex with regard to (joint) derogations and authorisations. A simpler approach with fewer steps is needed to increase efficiency. Option 2 should also introduce the improvements considered for the authorisation and restriction scheme proposed for Option 1.

Option 2A

• Some public authorities’ representatives highlighted that having two annexes might be confusing, as substances may be sometimes included in both lists. Several views highlighted the burden for authorities and industry and the time needed to adapt to the processes and enforcement complexities.

• Industry stakeholders thought that the proposal would not address competitive disadvantages for EU companies subject to the REACH regulation. For Annex XIV substances that are not present and therefore not restricted in the final product, production processes outside the EU cannot control the use of substances.

Option 3

• Many industry stakeholders indicated that authorisation has shown in the past years to have a positive impact on phasing out harmful substances, while putting limited burden on the authorities, as supporting data have to be submitted by the applicants.

5.2.6. Any other comment on the 4 options

• Industry and authority stakeholders explained that when comparing authorisation and restriction processes, restrictions require resources from authorities in the process of their development, whereas authorisations require resources once the application is submitted. If the new system includes an automatic uptake of substances to the candidate list once they receive harmonised classification under CLP, the authorisation system may get overloaded. However, at this moment there are too many uncertainties.

• According to the public authorities’ representatives, the analytical costs for enforcement, especially for complex restrictions are very high (e.g., approx. 2000
euros per sample for CMRs in textiles, and approx. 3000 per sample for phthalates, PAHs, MCCPs and SCCPs). These costs should be reflected somehow under the Forum work.

- National authorities suggested an amendment of REACH that allows Member States to also submit GRA-restriction proposals according to REACH Article 68(2) for substances, mixtures and/or articles.

- Some national authorities' representatives also argued that attention should be paid when comparing concepts such as "safe use" or "minimal exposure" as a basis for exceptions to restrictions, as this could undermine the core idea of essential use.
6. Annex 6: Public consultation

6.1. Methodology

In the framework of the project implementation, the Consortium developed six overarching questions on the reform of authorisation and restriction for the public consultation that feed into the large impact assessment study coordinated by another Consortium, led by Wood. The public consultation ran from 20 January to 15 April 2022. 770 contributions were received through the public consultation, and approximately 750 documents were uploaded by stakeholders. Out of the six questions, four were close-ended and two were open-ended questions.

Therefore, this section is divided into two sections. The first subsection summarises the quantitative results of the four questions, while the second subsection provides an overview on the responses to the open questions and the position papers provided by stakeholders.

The responses were used to triangulate the results of the interviews and online survey, in order to obtain more robust results underpinning the impact assessment exercise. The public consultation reached a broader set of stakeholders than the other stakeholder consultation activities. Using the results of the public consultation, the research team could test whether the limited number of respondents in targeted stakeholder consultation or interviews could cause a bias.

The results obtained were analysed after the conclusion of the public consultation and fed into the present study. Two different types of responses were received in the public consultation:

- Responses to close-ended questions,
- Responses to open-ended questions.

The study team analysed the responses to the closed-ended questions by relying on Excel. This allowed sharing the file used for the analysis with the Commission’s services as well as with the Consortium working on the overall impact assessment study for future use. The open-ended questions were analysed with a machine learning approach.

In analysing the replies to the public consultation, the study team ensured to take into account the few limitations of the exercise, such as the bias that some types of stakeholders can demonstrate linked to campaigns organised by certain interest groups.

6.2. GRA extension

Opinions of stakeholders on the extension of the GRA differed according to uses and substances that the extension should apply to. This can be shown in the responses to the question below, which differed for different uses and substances:

To what extent do you agree that, to ensure that citizens and the natural environment are more consistently protected, the most harmful chemical substances should be prohibited in the following products (even if this may cause the remaining safer products to have a lower performance and/or higher price)?

An extension to all products used by consumers, except for uses that are essential for society, was strongly supported by all groups.
Figure 1: Products used by consumers, except for uses that are essential for society

The extension to products used by professionals with the exemption of specific risk management measures drew a more mixed response with an equal share of respondents expecting positive than negative impacts.

Figure 2: Products used by professionals (e.g., hairdressers, cleaning staff), except if they are designed to ensure the safety during production, consumption disposal and recycling

In extension to all products used by professionals, except for uses that are essential for society, was strongly supported by all groups.
6.3. Reform options

As part of the consultation, respondents were also asked which impacts they expect from the different options:

Please assess how each option is expected to affect the following, on a scale from 1 (strongly negative, i.e. detrimental) to 5 (strongly positive, i.e. beneficial).

Option 1

- Businesses assessed the impact of option 1 on administrative burden as positive or neutral, while other stakeholders showed no clear preferences.

Figure 4: Option 1: Administrative burden on companies

- Public authorities and businesses thought that the costs for public authorities would decrease with option 1.
Across all stakeholder groups, more respondents indicated positive impacts for human health than negative. Many stakeholders from the business side thought that the impacts of Option 1 on human health would be neutral.

The structure of responses to impacts on the environment was very similar.
The impact of Option 1 on competitiveness had relatively mixed responses. While business respondents were equally split on positive and negative impacts, other respondents assumed a more positive impact.
Figure 8: Option 1: Competitiveness

- On the other hand, in all groups of stakeholders, more respondents expected a positive impact on innovation than a negative.

Figure 9: Option 1: Innovation and research

- The biggest advantage respondents saw was an increased legal certainty for companies.
Option 2

- Significantly more companies expected an increase in administrative burden than expected savings. Other stakeholder groups were more positive about the impacts on administrative burden of Option 2.

Opinions were more positive on the impact on the burden for public authorities. More positive responses dominated here in all stakeholder groups.
The impacts on human health of Option 2 drew very mixed responses. Positive and negative responses were balanced, while the neutral option was dominant especially in business.

A very similar structure of responses was given for the environmental impacts.
- Businesses more often expected a negative impact on competitiveness than positive. The responses of other stakeholder groups were more mixed.
- A very similar structure of responses was given on the impact on innovation.
• Businesses also did not respond very favourably to the impact of Option 2 on legal certainty. More businesses assessed the impact to be negative or very negative.
Option 3

- The expectation of companies regarding Option 3 and its impacts on administrative burden was very mixed. About as many companies expected an increase in costs than a decrease.

The expectations on the impacts on the costs of public authorities were more positive. In all groups, more respondents expected a positive impact on costs.
The majority of respondents of all groups expected a neutral impact on human health or they did not know. Of the remaining respondents, more expected a negative impact than a positive.

The responses on the impact on the environment were very similar.
- Companies expected more often a negative impact on competitiveness than positive.
- The same was true for the expected impact on innovation and on legal certainty.
6.4. Open questions and position papers

Two of the open questions in the public consultation were about the subjects of this study, (i.e., the options to reform authorisation and restrictions and the extension of the GRA). Additionally, many participants provided position papers, which were analysed by the team. The following key points were mentioned in the responses to the open questions and in the position papers.

6.5. General points on the reform of authorisation and restrictions

Stakeholders pointed out the following key arguments to be considered in the reform options:

- **Prioritisation**: For many industry and public authority stakeholders, one key aim of the reform should be to strengthen the prioritisation process of focusing the work on the most harmful substances and uses. Different suggestions were made to achieve this aim, such as transforming the SVHC list into a real waiting list for substances to collect all the information necessary for this prioritisation.

- **Speed and costs of processes**: There was also a broad agreement from authority and industry stakeholders that authorisation processes take up a lot of resources and that those processes should be speeded up and made less resource intensive. The discussion whether the proposed options would achieve those goals was very mixed. Many concerns were voiced that the regulatory capacities would be overwhelmed on the regulator and industry side if the processes are changed too much.

- **Data collection**: Several industry stakeholders pointed out that the data collection costs are the most important cost category especially in authorisation processes.

- **Authorisation**: Many industry stakeholders made the case for keeping authorisation processes. The key arguments for maintaining the process were:
  - Stakeholders thought that the authorisation process is established and tested and has become more efficient over time. Abandoning those experiences, and the learning processes involved in them and developing new procedures instead, is likely to cause considerable transition costs.
  - Many industry stakeholders also pointed out that, especially for professional users, authorisation processes were assessing the risks of the use and not only the hazard of the substance. The stakeholders thought that this is an efficient process for hazardous substances where a safe use can be ensured. There was a widely voiced concern by industry stakeholders also in connection to the extension of the GRA. In their view, going away from a risk-based approach (as in the authorisation process) to a regulation based on hazards would decrease the effectiveness and efficiency of chemical regulation.

- **Interlinkages with the essential use concept**: Many industry stakeholders pointed out that it is impossible to assess the impact of the different options without knowing more details on the essential use concept that will be applied for derogations. Some stakeholders missed the overall concept linking the reform options for authorisation and restriction, the extension of the GRA and the essential use concept.
• **Derogations for safe uses:** Several stakeholders (mostly industry but also others) outlined that not only derogations for essential use should be considered but also derogations for safe use, if RMM can ensure that a hazardous substance can be handled safely.

• **Articles:** Some industry and other stakeholders explained that current REACH processes impede their competitiveness vis-à-vis non-EU countries. This is an issue mainly for substances used or present in articles. They consider that this key challenge is not addressed by any of the options proposed as it relates to the requirements of importers and their enforcement. This can be relevant for the restriction process (competitors not following the restriction) or authorisations (competitors not applying for an authorisation even if they would have to).

• **Shifting administrative burden:** Many industry participants feared that all the options proposed could lead to a shift of the administrative burden from authorisation processes to restriction processes and not really to a reduction of administrative burden.

### 6.6. Specific points on the four options

Additionally, respondents provided specific comments on the options proposed. It is important to note that at the time of the consultation not all details on the options were available to stakeholders, which were provided in increasing detail in other documents such as CA/03/2022, CA/19/2022, and CA/45/2022 over the first half of 2022. For this reason, some of the comments of stakeholders could be already considered outdated and have been taken into account in the further development of the options.

Due to the above, many respondents pointed out that an assessment is difficult without more details available on the options.

**Option 1**

• **Regulatory certainty:** Many industry stakeholders favoured Option 1 as the option that would provide the least disruption to the regulatory framework. Respondents thought that the current authorisation and restriction processes have seen a lot of development and learning over the last 10 years and that those learning processes should not be abandoned.

• **Role of authorisation:** Industry respondents were especially concerned about abandoning the authorisation process. They thought of it as a tried and tested process to assess both the hazards and the risks, while also assessing the potential measures to control and limit risk. Abandoning this process would in their opinion lead to high costs and less effective and efficient regulation of chemicals.

• **Risk-based approach and socioeconomic assessment:** Related to these concerns, many industry stakeholders suggested that a risk-based approach and socioeconomic assessments should remain an important part of the regulatory system. The main argument for including the risk-based approach was that too many substances that do not pose a risk for the environment would be banned without it (as the RMMs are efficient). This would mean that GRA restrictions would result in significant costs for society (product withdrawals and substitution costs), without justifying the human health and environmental benefits.

• **Regulatory flow and prioritisation:** Another important consideration of industry and authority stakeholders was regulatory flow and prioritisation. Respondents argued that a reform of current processes that enables an efficient prioritisation process would be most likely achieved with Option 1.
Option 2 and 3

- **Details:** Many or even most participants reported that both Option 2 and Option 3 would require a considerable amount of extra details before they can be assessed properly. They would both need to be thoroughly assessed, as they would both pose a significant change to the current system.

- **Restrictions:** In both options and especially in combination with an extension to the GRA, respondents expected more restrictions, which would lead to more substitution and product withdrawal costs. More expected restrictions would increase the burden on companies having to adapt their portfolio. This needs to be taken into account.

- **Prioritisation process importance:** For these two options, stakeholders especially pointed out that prioritisation is very important if the significance of the restriction process increases. Stakeholders asked how the candidate list would be further developed and how the prioritisation process would ensure that restrictions would focus primarily on the most harmful substances.

- For Option 3, all respondents were least clear about the organisation of the process. They asked about the derogations and the conditions of derogations (essential use or safe use), which was most important in their view for the assessment of this option.

- Overall, industry participants were very critical of Option 3 mainly because of the abandonment of the authorisation process, which they thought would cause many additional adaptation burdens without much benefit.

Extension of the GRA

Respondents commented in the following way about the suggestion to extend the GRA to more hazard classes and to professional uses:

- **Stepwise introduction needed:** Many participants from industry but also from authorities commented that the effects are very hard to predict, as knowledge of all affected substances, the risks in their different applications, and the socioeconomic costs of their withdrawal, is not currently available. For these reasons, they thought that a stepwise introduction of the approach should take place, starting with the substances and uses where knowledge is already developed, and collecting more evidence on other areas over time.

- **Hazard versus risk:** Many participants voiced concern that the extension of the GRA would mean a general shift away from risk assessment and a limitation to hazard assessment. The participants thought that such a move would make the REACH Regulation less effective, as the restrictions might focus on hazardous substances which pose no significant risk, while other less hazardous substances that pose larger risks (due to no available RMMs) would not be regulated or restricted.

- **Professional uses:** Several participants from industry questioned the approach of extending the expansion of the GRA to professional uses in principle. Their key arguments focussed on the existing RMMs that would manage the risk of many substances in professional use, making the restriction superfluous (as it would not reduce risk further) and in some cases very expensive.

- **Scientific assessment procedures:** Related to the points above, industry and some authority participants voiced the concern that scientific assessment
procedures of the risk of substances and the socio-economic impacts of substitution should not be abandoned in order to ensure effective and efficient regulation.

- **Signalling for substitution:** Participants from authorities and NGOs supported the extension of the GRA, especially because it would provide a stronger and clearer incentive for substitution. The argument was that by restricting whole hazard classes, the industry would have more incentives to search for a greater amount of substitutes, and not be limited to similar substances that may also have hazardous effects. Although substitution would become more difficult, it would also be more successful in terms of risk reduction if properly applied.

- **Using examples of other legislation (cosmetics):** Several authority participants pointed out the experiences of other legislations (e.g., cosmetics) and the available experience within REACH (CRMs) in the drafting and implementation of the extension.

- **PMT and vPvM:** Some participants (especially from the water industry) pointed out that the GRA should also be extended to PMT and vPvM substances, due to their threat to water quality and the high costs of treatment they cause.

- **Essential use concept:** Many industry and authority stakeholders said that an assessment of the GRA extension is difficult to impossible without a good understanding of the essential use concept that will be used to define derogations from the restrictions. The economic consequences of more general restrictions are hard to assess, without knowing how essential uses are protected and how the concept is applied in practice.

- **Safe use concept:** Some industry stakeholders criticised that derogations for safe uses were not mentioned in the available text. They thought that derogations for safe use are necessary for many substances where existing RMMs manage the risks of the use sufficiently. Especially if professional uses are included, this consideration was thought to be very relevant.
7. Annex 7: Interviews on enforcement

7.1. Methodology

In addition to the interviews mentioned in sections 2.1 and 2.4, two interviews on enforcement were carried out in mid-June 2022 with experts from ECHA involved in the work of the Forum. These interviews aimed to collect information on the impact of the different options on enforcement, effectiveness, costs and the work of the Forum.

The two interviews brought the following key messages on the future role of the Forum. Two options were discussed in addition to the current role of the Forum:

Table 2: Role of the Forum (F1, F2)

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
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<tbody>
<tr>
<td>F1</td>
<td>The Forum becomes a committee providing “agency opinions” with the equivalised status of RAC and SEAC. Opinions would be provided on AAs/general derogation requests/individual derogation requests and on restrictions proposals under Article 88(1). Note for AAs, the advice would be on additional conditions proposed by RAC or SEAC and not likely to be required in all cases.</td>
</tr>
<tr>
<td>F2</td>
<td>The Forum continues to give advice for restrictions but also for authorisations (note this is not relevant for all options). These would be provided when draft opinions are uploaded for comment by the Committee members. Hence, the Forum would be involved whenever RAC and SEAC give an opinion (e.g., always for restrictions and where necessary for individual authorisations). The advice would focus on enforceability of recommendations for authorisation and RMMe/operational conditions proposed by RAC or other conditions proposed by SEAC at draft opinion stage. This would be done for groups of substances or uses, rather than for every AA. Note this may not always be necessary and this should not prolong the opinion-making process of RAC and SEAC.</td>
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7.2. Results

The following key comments were provided during the interviews:

- A clear advantage from an increased role of the Forum in the restriction process would be the increased clarity on how the advice of the Forum should be treated. This would imply that restrictions are better suited for implementation by enforcement authorities and easier to comply with for companies as the restriction text will be clearer in respect to enforcement.
- In an ECHA report, it was found that the Forum advice was mostly implemented in the final restriction text and it was accepted as useful. If the restriction text is clearer, companies struggle to find grey areas and thus have to comply more closely, which should create a better base for enforcement.
- Another clear benefit would be an increased transparency. If the advice is publicly available, companies and all other stakeholders can see how the Forum is thinking about the enforcement process. This could improve the communication and stakeholder engagement process. This will be especially advantageous for the Commission as well as RAC and SEAC and companies.
- Any increased role of the Forum will require some extra budget. However, these costs are negligible compared to the costs of poorly drafted restrictions not robustly taking enforcement issues into account.
• If the opinion of the Forum would receive the same status as the RAC and SEAC, there would be a major resource impact compared to the current process. It would require having co-rapporteurs to draft the Forum’s advice, which would double the effort. It would also require further coordination with RAC and SEAC. If RAC, SEAC and the Forum were to become equal bodies, the coordination of all three working strands would be much more complicated than currently, with significant resource implications for the Forum and the agency.

• Some doubts were raised regarding the first of the options which would give the Forum the role of providing a third agency opinion (see option F1 in Table 2). The opinion was that this could add a lot of costs (mainly due to coordination with RAC and SEAC) to the process, which would not necessarily be met by increased benefits. However, it was strongly supported to give the opinion of the Forum more weight by making it publicly available.

• However, a combination of the two options was supported. The Forum should have the responsibility of advice on authorisation.

• The Forum should have a role in providing advice before the REACH committee discusses the decision on restrictions as well as authorisations. Especially when these processes are combined, the Forum should have a role in that.

• According to the interviewees, another potential driver of costs for the Forum is the upcoming PFAS restriction. A significant amount of advising work is to be expected on enforcement aspects here.21

• At the moment, the interviewees did not see a large difference in hierarchy between RAC and SEAC on the one hand, and the Forum on the other hand. The work performed is of equal importance. However, organisational differences between these bodies exist. RAC members are nominated on a personal level (even though some of them are nominated by Member States), while Forum members represent their Member State.

• If the Forum would receive a greater role, more capacity is needed for Member States. A greater role will also result in an increased need for support from ECHA. In the future, the Forum will require additional working time due to the increased workload. The Commission would also need more internal capacity to exchange with the Forum.

• Benefits of the outcome of the current Forum process are manifold. It is better for the quality of enforcement for companies, because they will deal with clearer legislation. Better implementation of chemical regulation, enforcement, and compliance, will yield benefits for health and environment, as there will be less chemical and hazardous substances in products and less contamination of the environment. Having some input on the process would be beneficial in making it more enforceable, but the Forum inputs have a different topic as they focus on feasibility, while RAC and SEAC opinions are, respectively, on risks and socioeconomic impacts.

• The interviewees therefore suggested not providing an equal role to the Forum’s opinion, but making it publicly available. The benefits would be exactly the same, but the costs would be a fraction, as the coordination with RAC and SEAC and the resources/costs are not the same, both for ECHA and Member States.

21 It should be noted that a restriction dossier for PFASs is being prepared by five Member States based on Article 68(1) and is expected to be submitted to ECHA in January 2023. Therefore, this comment relates to the baseline and not to the options under consideration in the impact assessment.
8. Annex 8: Workshops

8.1. Methodology

All four workshops were organised as one-day events. The workshops always started with a presentation of the policy background, and objectives and then provided an overview on key results and assumptions of the study. Following that, the active participants were invited to join break-out groups that focused on specific topics or sectors.

A report outlining the proceedings and the results was produced and published following each workshop.

8.2. Results

First and second workshops

On 9 and 12 November 2021, two workshops on the reform of REACH authorisation and restriction were organised. The first hybrid workshop of 9 November was organised by the Commission with the Slovenian Presidency in Brdo (Slovenia) and online, and it included representatives of the EU Member States.

The second hybrid workshop on 12 November was organised by the Commission in Brussels (Belgium) and online. The participants were representatives from industry, NGOs, law firms, companies, trade unions and other EU associations.

The workshops’ main objective was to inform and familiarise Member States’ representatives and stakeholders with the initial approach of the Commission’s services on the planned reform of the REACH authorisation and restriction system, as well as other elements under scrutiny in the impact assessment. The workshops intended to get initial reactions from stakeholders to help refine policy options and to inform the Commission’s impact assessment.

Third workshop

A third online workshop on the GRA was held with participants online on 21 March 2022 and focused on the results of a “use mapping” exercise. This use mapping involved detailed analysis of registration information to identify the number of substances that have proven or assumed hazardous properties that may, depending on the later design of the REACH regulation, qualify them to be regulated via the GRA. These data form the basis of the impact assessment work.

The objective of the workshop was to validate the use maps prepared by the study team and collect feedback. In order to do so, the study team first presented the preliminary findings followed by a presentation of the issues to be discussed and addressed in the workshop and during the discussion sessions.

Fourth workshop

Finally, a fourth online workshop was organised on 27 June 2022. This workshop aimed to validate the findings of the assessment of impacts of the extension of the GRA. Similarly as with the third workshop, stakeholders involved in previous stages of consultations were invited, and the list of invited stakeholders was relevant to the topic at hand.
The study team presented their results of the assessed impacts of the extension of the GRA. These results were then discussed with the stakeholders in a Q&A and feedback session.

9.1. Methodology

From 3 March until 6 May 2022, a survey among companies, with a focus on SMEs, was conducted. This included questions, not only on the GWA extension and the reform of authorisation, but also on broader questions regarding the REACH reform. Overall, 193 companies, including 168 SMEs, responded to the survey. Results concerning the extension of GWA and the reform of authorisation and restriction are summarised below.

9.2. Results

Extension of the GWA

In the SME panel, SMEs voiced concerns about the restriction of specific substances based on the extended GWA and especially about professional uses. The impact on administrative burden was thought to be particularly negative for CRMs in professional uses, STOTs in professional uses, and PBTs in professional uses. Across the board, the assessment of an inclusion of professional uses was more negative than the assessment of an inclusion of consumer uses. The results are summarised in the table below.

Table 3: SME Panel – Extension of the GWA

<table>
<thead>
<tr>
<th>Q10a. Would you expect a very negative (-2), negative (-1), neutral (0), positive (1) or very positive (2) impact on your company if generic restrictions were introduced for the hazard classes listed below? For each row (i.e. hazard class) and each column (i.e. type of impact), please indicate the level of impacts that you expect for your company (-2, -1, 0, 1, 2). If you don’t know, you don’t have to enter anything in the respective row(s).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Averages</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances for consumer uses</td>
</tr>
<tr>
<td>Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative substances for professional uses</td>
</tr>
<tr>
<td>Carcinogenic, mutagenic or toxic for reproduction substances for professional uses</td>
</tr>
<tr>
<td>Endocrine disruptors for human health and environment for consumer uses</td>
</tr>
<tr>
<td>Endocrine disruptors for human health and environment for professional uses</td>
</tr>
<tr>
<td>Substances with specific target organ toxicity, single exposure (STOT SE) and repeated exposure (STOT RE) for consumer uses</td>
</tr>
<tr>
<td>Substances with specific target organ toxicity, single exposure (STOT SE) and repeated exposure (STOT RE) for professional uses</td>
</tr>
<tr>
<td>Immunotoxic and neurotoxic substances for consumer uses</td>
</tr>
<tr>
<td>Immunotoxic and neurotoxic substances for professional uses</td>
</tr>
</tbody>
</table>
Q10a. Would you expect a very negative (-2), negative (-1), neutral (0), positive (1) or very positive (2) impacts on your company if generic restrictions were introduced for the hazard classes listed below? For each row (i.e. hazard class) and each column (i.e. type of impact), please indicate the level of impacts that you expect for your company (2, 1, 0, -1, -2). If you don’t know, you don’t have to enter anything in the respective row(s).

<table>
<thead>
<tr>
<th></th>
<th>Administrative costs</th>
<th>Regulatory innovation</th>
<th>Competitiveness</th>
<th>Access to market</th>
<th>Workers’ safety</th>
<th>Overall average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory sensitisers for consumer uses</td>
<td>-0.37</td>
<td>0.28</td>
<td>0.22</td>
<td>0.10</td>
<td>0.64</td>
<td>0.18</td>
</tr>
<tr>
<td>Respiratory sensitisers for professional uses</td>
<td>-0.57</td>
<td>0.09</td>
<td>-0.07</td>
<td>-0.05</td>
<td>0.67</td>
<td>0.02</td>
</tr>
<tr>
<td>Overall average</td>
<td>-0.56</td>
<td>0.11</td>
<td>-0.02</td>
<td>0.01</td>
<td>0.72</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Option 1

It is worth noting that the options were in a state of development when the SME panel was conducted. Therefore, companies were not consulted on all of the final elements included in the impact assessment.

Overall, the measures discussed regarding Option 1 scored best in respect to market access (for SMEs) and competitiveness. Most popular with SMEs were measures which decreased the administrative burden for SMEs, for example a clarification of criteria, lighter information requirements for SMEs and transitional arrangements or facilitation of subsequent submissions. The results are summarised in the table below.

Table 4: SME panel – Option 1

<table>
<thead>
<tr>
<th>Averages</th>
<th>Administrative costs</th>
<th>Regulatory innovation</th>
<th>Competitiveness</th>
<th>Access to market</th>
<th>Workers’ safety</th>
<th>Overall average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarification of legislation</td>
<td>-0.14</td>
<td>0.19</td>
<td>0.10</td>
<td>0.24</td>
<td>0.43</td>
<td>0.16</td>
</tr>
<tr>
<td>Lighter information requirements for SMEs</td>
<td>0.68</td>
<td>0.49</td>
<td>0.69</td>
<td>0.61</td>
<td>0.25</td>
<td>0.52</td>
</tr>
<tr>
<td>Introducing a completeness check and strengthening the conformity check</td>
<td>-0.29</td>
<td>0.13</td>
<td>0.14</td>
<td>0.14</td>
<td>0.28</td>
<td>0.12</td>
</tr>
<tr>
<td>Clarifying procedures for the Commission to introduce changes to authorisations</td>
<td>0.18</td>
<td>0.19</td>
<td>0.22</td>
<td>0.27</td>
<td>0.25</td>
<td>0.22</td>
</tr>
<tr>
<td>Introducing the possibility of transitional arrangements to cease the use smoothly</td>
<td>0.61</td>
<td>0.65</td>
<td>0.67</td>
<td>0.68</td>
<td>0.26</td>
<td>0.55</td>
</tr>
<tr>
<td>Simplified procedures for cases where the risk is likely to be more controlled (e.g., use of closed systems, if the use is specific (e.g., legacy spare parts), if exposure/emissions/quantity used are below a certain threshold)</td>
<td>0.63</td>
<td>0.42</td>
<td>0.61</td>
<td>0.68</td>
<td>0.26</td>
<td>0.49</td>
</tr>
<tr>
<td>Clarifying the criteria for uses exempted from authorisation (e.g., research and development, intermediates)</td>
<td>0.54</td>
<td>0.63</td>
<td>0.48</td>
<td>0.55</td>
<td>0.40</td>
<td>0.52</td>
</tr>
<tr>
<td>Facilitating submission of subsequent applications for authorisation that rely on existing applications/authorisations for the same use</td>
<td>0.67</td>
<td>0.50</td>
<td>0.61</td>
<td>0.59</td>
<td>0.33</td>
<td>0.54</td>
</tr>
<tr>
<td>Overall average</td>
<td>0.37</td>
<td>0.39</td>
<td>0.41</td>
<td>0.45</td>
<td>0.31</td>
<td>0.39</td>
</tr>
</tbody>
</table>
Option 2 and Option 3

Overall, the expectations of SMEs regarding the different measures suggested under Option 2 and Option 3 (and on some cross cutting measures) were slightly positive with some notable exceptions.

For most impact types, the expectations were slightly positive with the exception of workers’ safety where the assessments were more positive on average. The measures of Option 2 and 3, which were assessed most positively, were the joint requests for derogations, essential use derogations and the focus on health and safety regulations for industrial users. A very negative assessment was provided for the inclusion of fees for substances in the candidate list. The results are summarised in the table below.

### Table 5: SME panel – Option 2 and Option 3

| Q9. Do you expect a very negative (-2), negative (-1), neutral (0), positive (1) or very positive (2) impact on your company from the measures listed below, compared to the current situation? For each row (i.e., measure) and each column (i.e., type of impact), please indicate the level of impacts that you expect for your company (-2,-1,0,1,2). If you don’t know or don’t have an opinion, you don’t have to enter anything in the respective row(s). |
|---|---|---|---|---|---|
| Averages | Administrative costs | Research and innovation | Competitiveness | Access to market | Workers safety | Overall average |
| Option 2. Marging the authorisation list with restriction list | 0.20 | 0.15 | 0.18 | 0.18 | 0.21 | 0.18 |
| Option 2. Allow joint requests by companies for derogations from generic restrictions applicable to the entire use | 0.50 | 0.38 | 0.41 | 0.45 | 0.14 | 0.38 |
| Option 2. Allow individual requests by companies for derogations from restrictions/authorisations | 0.23 | 0.31 | 0.39 | 0.45 | 0.18 | 0.31 |
| Option 3. Use of chemicals of concern by consumers and professionals (e.g., hairdressers) are regulated by generic and specific restrictions under REACH | 0.01 | 0.09 | 0.06 | 0.06 | 0.44 | 0.13 |
| Option 3. Exposure to chemicals of industrial workers are regulated only by occupational health and safety rules (not by REACH) | 0.54 | 0.19 | 0.36 | 0.41 | 0.57 | 0.41 |
| Option 3. Industrial emissions of chemicals are regulated by the Industrial Emissions Directive (not by REACH) | 0.32 | 0.27 | 0.28 | 0.34 | 0.37 | 0.32 |
| Cross-cutting measure: Grant authorisations and/or derogations from restrictions for essential use (necessary for health, safety or critical for functioning of society AND no available alternative) | 0.36 | 0.33 | 0.39 | 0.42 | 0.33 | 0.37 |
| Cross-cutting measure: Downstream users have to notify authorities and provide information (e.g., uses, tonnage, exposure) on substances included in the candidate list | -0.48 | -0.09 | -0.20 | -0.21 | 0.25 | -0.15 |
| Cross-cutting measure: Downstream users have to pay a notification fee for substances in the candidate list | -0.88 | -0.39 | -0.63 | -0.63 | 0.10 | -0.49 |
| Overall average | 0.09 | 0.14 | 0.14 | 0.16 | 0.29 | 0.16 |

List of abbreviations

ACSH  Advisory Committee for Safety and Health at Work
AgA  Analysis of Alternatives
CARACAL  Competent Authorities for REACH and CLP
CLP  Classification, Labelling and Packaging) Regulation (EC) No 1272/2008
DEHP  Di(2-ethylhexyl) phthalate
DUs  Downstream users
ECHA  European Chemicals Agency
ED  Endocrine disruptors
Forum  Forum for Exchange of Information on Enforcement
IED  Industrial Emissions Directive 2010/75/EU
NPE  Nonylphenol ethoxylates
OECD  Organisation for Economic Co-operation and Development
OPE  Octylphenol ethoxylates
OSH  Occupational Safety and Health legislation
PIC  Prior Informed Consent Regulation
POPs  Persistent Organic Pollutants Regulation
R&D  Research & Development
RAC  Committee for Risk Assessment
REACH  Registration, Evaluation, Authorisation and Restriction of Chemicals
RMME  Risk Management Measures
RMOP  Risk Management Option Analysis
RoHS  Restriction of Hazardous Substances
SAICM  Strategic Approach to International Chemicals Management policy framework
SCIP  Substances of Concern in articles as such or in complex objects (Products) established under the Waste Framework Directive
SEAC  Committee for Socio-economic Analysis
SMEs  Small and medium-sized enterprises
SVHCs  Substances of Very High Concern
10.1. Executive summary

The Slovenian presidency of the Council of the EU and the European Commission held a workshop on the reform of REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Authorisation and Restriction at the Brdo Estate (Slovenia) and online simultaneously on 9 November, 2021.

The workshop was organised in the context of the planned reform of the REACH authorisation and restriction system based on the 2018 REACH Review, as announced in the Chemicals Strategy for Sustainability. The planned reform aims to build on the positive experiences in implementing the REACH authorisation and restriction processes and address their current weaknesses and inefficiencies.

Overall, the main objectives of the workshop were to inform competent authorities of Member States with the initial thinking of the Commission services on the planned reform of the REACH authorisation and restriction system, as well as other elements that will be assessed in the impact assessment. The workshop was an opportunity for national competent authorities to offer their initial responses and to help refine the policy options and inform the Commission’s impact assessment. To this end, representatives of a range of Member States participated in the workshop.

At the workshop, representatives of Member States Competent Authorities were assigned to one of four “world café tables”, which discussed eight main topics. A summary of these discussions in each interactive session is presented in chapter 3 of this workshop report. The key elements discussed in the interactive sessions revolved around (i) problem analysis and objectives of the reform, (ii) three defined policy options under scrutiny of the REACH revision (three separate discussions, each one dedicated to one option), (iii) level of ambition, advantages and disadvantages of each policy option, (iv) national authorisations, international level playing field and export bans, (v) interface of REACH with other legislation, (vi) innovation and how to support substitution, improving enforceability and impact on SMEs.

Problem analysis and objectives of the reform

Participants generally agreed that the background document of the European Commission (see Annex 5.2 of this document) provides a comprehensive and relevant description of the achievements and problems of the current authorisation and restriction processes. They agreed that the authorisation process can be perceived as disproportionate (very small quantities and limited risk reduction in some authorisations) and burdensome, especially for small and medium-sized enterprises, while the restriction process is considered burdensome for Member States. In addition, participants agreed on the necessity to accelerate the substitution of hazardous substances.

Some participants emphasised that the information provided in applications for authorisation contained varying levels of detail depending on whether they are “upstream” (too generic) or “downstream”. Several participants considered that the authorisation system to be “rigid” and that it should be made more efficient. Many participants highlighted the need for prioritisation of requirements and the depth of the assessment, hence suggesting a reduction of the burden where information is not indispensable while maintaining a high level of scrutiny of key elements. Participants agreed that there is currently an insufficiently level playing field between EU and non-EU companies, in particular when the SVHC is not present in the final product.

Some participants argued that the problem definition in the Commission’s analysis should be substantiated by data. Moreover, they suggested further analysis of the motivation of companies to substitute SVHCs. Some pointed out that there is currently not enough exchange between applicants and alternative providers in the authorisation system. Other
participants raised several issues that require clarification, for instance on the scientific assessment. Finally, some participants suggested that issues related to imported articles produced with recycled materials should be explored further.

Discussions around policy options
To better structure the impact assessment, the Commission has identified four main options, including the baseline option (option 0):

- Option 0: Maintain the current REACH Regulation as implemented from June 2007 without the revision;
- Option 1: Elements for simplification under the current authorisation system;
- Option 2: Merging authorisation and restriction;
- Option 3: Removing the authorisation title from REACH, role of restrictions, role of the candidate list; notification obligations for uses after SVHC identification.

Overall, participants agreed that it would be ideal to take the best elements of Option 1 and Option 2 and merge them. Participants regarded the list of issues for improvement in the Commission background paper as a good starting point for simplification. Further, they emphasised that the burden of proof should continue to be with industry. Participants added that information on uses, and exposure should be generated earlier in the process, for example linked to the Candidate listing so as to allow identification of potential concerns and also early exchanges on alternatives.

Some participants emphasised that the general possibility of banning substances on the basis of their hazardous properties, which is the ‘spirit’ of the authorisation system, should be kept. Many participants expressed concerns that merging restriction and authorisation might increase rather than decrease complexity. Some expressed their preference for keeping the two processes separate. Others considered Option 2 interesting and worth exploring. Further details should be worked out. Participants highlighted that joint derogations could offer advantages but that individual ones could be necessary in certain circumstances.

There was no general support for the removal of the authorisation title as foreseen in Option 3. Some participants stated that if Option 3 were to be considered, some key elements of the current authorisation system must be maintained – e.g., the candidate list.

National authorisations, international level playing field and export bans
A clear majority of participants were against national authorisations as it would reduce harmonisation in the EU Internal Market and increase the burden for national authorities.

Participants confirmed the need for an international level playing field. Participants stated that extending the scope of existing conventions should be considered – e.g., Prior Informed Consent Regulation, Persistent Organic Pollutants Regulation and the co-operation within the Strategic Approach to International Chemicals Management policy framework and the OECD should be further developed. Moreover, participants indicated that the sustainable product initiative could be used. They also suggested applying a certification scheme for SVHC – e.g., for imported cosmetics and to lower limit value in restriction (<0.1 %).

Regarding export bans, participants were in favour of including manufacturing in the authorisation procedure. At the same time, international fora should be used to encourage adoption of similar rules internationally – e.g., through extending the scope of existing conventions. The approach of the Basel Convention on the export of waste should be explored for SVHCs listed under REACH.

Interface REACH – other legislation
Participants agreed that REACH-OSH (Occupational Safety and Health legislation) is the most important interface. There is the potential for regulatory conflicts with OSH-legislation, both for authorisations and for restrictions. Stronger integration could provide an added value, but legal consequences and implications for companies should be carefully analysed. Most participants were in favour of harmonising limit values to prevent divergence between OSH legislation and REACH.

Clear criteria are needed to determine the most appropriate legislative route. Risk Management Option Analysis (RMOA) is an important tool in deciding the appropriate regulatory route at the beginning of the regulatory process.

Moreover, participants agreed on the necessity of holding joint REACH-OSH higher level discussions, e.g., using CARACAL (competing authorities for REACH and CLP), or the Advisory Committee for Safety and Health at Work (ACSH). Other possible interfaces to be further explored were mentioned, such as the Industrial Emissions Directive.

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

Participants agreed on the importance of strengthening incentives for substitution. They also agreed on increasing the role of the Forum for Exchange of Information on Enforcement, which should be more involved in later stages of the assessment of proposals, as restriction proposals typically change during the opinion process. In particular, the potential change regarding the role of the Forum should not delay the process. Some participants considered that the main issues on enforceability are related to the availability of standard analytical methods for measuring the presence of substances. In their view, this was an issue to be tackled by standardisation committees.

On the use of financial instruments, some participants suggested that the use of financial instruments could provide an increased incentive. However, other participants were concerned that fees could create an additional burden to EU industry.

10.2. Introduction

10.2.1. General context and objective of the workshop

The Slovenian presidency of the Council of the EU and the European Commission held a workshop on the reform of REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Authorisation and Restriction at the Brido Estate (Slovenia) and online simultaneously on 9 November, 2021.

The workshop focused on the planned reform of the REACH authorisation and restriction system announced in the Chemicals Strategy for Sustainability. The agenda and background document of the workshop are added as annexes at the end of this report.

The policy options to revise the REACH Regulation, which are considered by the Commission, aim to:
- free resources to tackle a wider range of more relevant chemical risks;
- make the authorisation and restrictions processes more efficient and effective;
- achieve a higher level of protection of human health and the environment from the risks of the most harmful substances; and
- give clearer signals and more planning security to companies.
The main policy options considered are the following:

- Option 1: keep authorisation provisions with clarifications and simplifications;
- Option 2: merge authorisation and restriction provisions; and
- Option 3: remove the authorisation title from REACH.

In the above context, the main objectives of the workshop were to familiarise the competent authorities of Member States with the initial Commission thinking on the planned reform of the REACH authorisation and restriction system, including on the policy options under consideration, and to receive their feedback. This feedback will help to further develop and refine the policy options and to inform the Commission’s impact assessment.

A similar workshop with a range of stakeholders (including trade unions, industry associations, companies and NGOs) was held on 12 November, 2021. The two workshops are part of wider consultations on the reform of the authorisation and restrictions system. In particular, the discussion will continue in CARACAL meetings in January and March, 2022, and others may follow, as necessary.

As part of the wider consultations planned for the impact assessment of the revision of the REACH Regulation, an Open Public Consultation will be launched (tentatively from January until April 2022), as well as targeted consultations in the form of questionnaires, and follow-up interviews. Several contractors are supporting the Commission in the impact assessment work. For the revision of authorisation and restriction under REACH, a specific study is being carried out by a consortium of consultancies (VVA Consortium).

10.2.2. Workshop organisation

The workshop primarily focused on a discussion of key topics on the reform of authorisation and restriction processes under the REACH Regulation. The agenda of the workshop is presented in Annex 1 of this report.

The Commission invited the representatives of Member States to provide feedback to the questions presented in the background document (annex 2) during the ‘world café’ table discussions. Participants were allocated to four tables and every table had 30 minutes to discuss each of the topics. A moderator and a rapporteur were allocated to each of the four subjects on the different tables. A summary of discussions was reported back to the plenary session. While the opening and closing sessions of this workshop were web streamed and made accessible to any registered participant, the world café tables were accessible only to the participants of that table.

After the opening session, two rounds of the world café tables were organised, each running for two hours. The first round took place in the morning and the second round in the afternoon.
Topics discussed during the **morning session** of the world café tables:
- Problem analysis and objectives
- Option 1: Elements for simplification under the current authorisation system
- Option 2: Merging authorisation and restriction
- Option 3: Removing the authorisation title from REACH; rules of restrictions, role of the candidate list; notification obligations for uses after SVHC identification

Topics discussed during the **afternoon session** of the world café tables:
- Level of ambition, advantages/disadvantages of Options 1, 2, 3;
- National authorisations, international level playing field and export bans;
- Interface REACH-other EU legislation; and
- Innovation and how to support substitution, improving enforceability and impact on SMEs.

The last part of the workshop focused on feedback from the participants on the eight topics discussed. A summary of the discussions per topic was presented by rapporteurs of the world café tables.

Finally, the participants were invited to submit their written contributions to the Commission by email to: GROW-ENV-REACH-REVISION@ec.europa.eu and to contribute to the **Public Consultation**, which is tentatively planned to run from January until April 2022. Furthermore, participants are welcome to provide answers to a questionnaire prepared as part of the **targeted consultation** on the reform of authorisation and restriction, planned to occur between February and April 2022. This targeted consultation may be followed up by individual interviews with stakeholders.

### 10.2.3. Participants

The Slovenian Presidency and the European Commission invited representatives of Member States to take part in the workshop. The following Member States were represented: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Romania, Spain and Sweden. In addition, Commission staff, ECHA staff and consultants from VVA participated in the workshop as moderators and rapporteurs for the world café tables.

### 10.3. World café tables

This section presents the key points that emerged from the discussions on each of the eight topics and summarises them by 1) common views, 2) diverging views and 3) additional points discussed among participants.

A background document was sent to the workshop participants (see **Annex 2 of this report**) to present the main issues of the REACH Regulation’s authorisation and restriction process, as identified by several documents such as the Commission’s inception impact assessment[22], the **REACH Review**[23], and several studies of the European Chemicals

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10.3.1. Problem analysis and objectives

For this topic, participants were asked the following questions: What is your view on the Commission's initial analysis of underlying drivers, in particular the analysis of the implementation of the current REACH authorisation and restriction processes and their achievements, problems and deficiencies? Are there missing elements?

10.3.1.1. Common views

Participants agreed that the background document prepared by the European Commission provides a comprehensive overview of the challenges and problems with the current implementation of the authorisation and restriction provisions under REACH and was considered to be relevant for the problem definition.

Concerning the current authorisation process, participants agreed on many points. Participants described the authorisation process as heavy, as it requires much effort sometimes for very minor quantities of substances and limited risk reduction in some authorisations, such as for OPEs and NPEs. Moreover, the upstream and downstream applications for authorisation require different levels of detail, which is considered to be unfair, as more details are required from downstream users that can also be SMEs with limited resources. Generally, the current procedures were considered burdensome for SMEs, both in terms of applying for authorisation and complying with authorisation and restriction decisions. In addition, participants stated that not requiring an authorisation for the manufacture of SVHCs for export represents an uncontrolled risk for both EU workers and the environment.

Participants agreed that there is an uneven playing field for EU-based companies as SVHCs can be present in imported articles, which are not covered by authorisations. This is particularly the case when the SVHC is not present in the final product (e.g., chrome plated articles).

At present, there is also not enough exchange between applicants and alternative providers in the authorisation system, and participants therefore agreed on the need for improvement in this area in order to accelerate substitution. Participants also agreed on the high level of complexity related to demonstrating detailed ‘unacceptable risk’ in restriction dossiers.

10.3.1.2. Diverging views

The discussions revealed two main diverging views. The first diverging view emerged from the discussion on whether authorisation applications included the level of information needed. Some participants believed that companies provided enough information on processes and uses in their applications for authorisation and that, thanks to authorisation, a lot of knowledge has been gained. On the contrary, other participants considered the information provided by companies as too ‘generic’ (e.g., concerning available alternatives), and they argued that there is a need for more data rather than less.

31 Notably the latest ECHA's study: "Causal impacts of the REACH Authorisation process on the use of substances of very high concern in the EU". ECHA. 2021 (forthcoming)
Several participants raised the issue that the authorisation system is resource intensive. While participants agreed that efforts should be made to improve process efficiency, some participants highlighted that rather than speaking about burden reduction the focus should be on the proportionality of the assessment. In other words, some highlighted that a burden reduction should be achieved while maintaining a high level of scrutiny, without lowering the protection of human health and the environment.

10.3.1.2.1. Additional points discussed

Some participants highlighted that the problem definition should be substantiated by data. Moreover, some suggested improving analysis and understanding of the motivation of companies to substitute SVHCs. Adding that the real driver behind substitution is linked to the existence of a market for alternatives.

Participants raised additional issues to be considered in the problem definition. For instance, in relation to the level of details expected in upstream applications for authorisations or in group restrictions, participants emphasised the need for clarification of what to expect from the scientific assessment and regarding how to manage uncertainties. Furthermore, concerning uses in SR&D (Scientific Research & Development) under authorisations, participants noted that more clarity should be provided on legal exemptions and on other EU legislation since there are different interpretations by companies. Some participants pointed out that the scarcity of information in registrations poses a challenge for authorisation and restriction.

Some participants also noted that more attention should be paid to the link between authorisations and restrictions. The existing procedure under article 69(2) of REACH was considered to have not been exploited sufficiently, since so far it has led to only a few restrictions. Moreover, it was suggested that evolution of the choice between authorisations and restrictions be assessed.

Additionally, some participants suggested that issues linked to recycling should be further explored – e.g., the issue of imported articles containing recycled materials (such as PVC), and possible unfair competition for EU companies.

Finally, participants also discussed some issues related to the European Chemicals Agency (ECHA) Committees. The fact that the RAC and SEAC opinion-making runs in parallel was considered to be an issue since SEAC relies on RAC’s assessments in several aspects. Additionally, participants noted that the Forum is only involved at the beginning of the process, although the final restriction might have different elements than the ones initially assessed by the Forum, highlighting that enforceability of restrictions is important.

10.3.2. Option 1: Elements for simplification under the current authorisation system

For this topic, participants were asked the following questions: What is your view on the Commission’s initial collection of elements for simplification of the current authorisation and restriction systems? Are important elements missing? To what extent would addressing those elements be sufficient to remedy the observed problems with authorisation and restriction?

10.3.2.1. Common views

Participants noted that the merits and difficulties of the current authorisation system are well understood. Overall, participants also shared the opinion that the requirements
for applications should be simplified when the risk is likely to be intrinsically more controlled (e.g., low quantities, SCC).

During the exchange, participants considered the list of issues for improvement in the Commission background paper as a good starting point in the quest for simplification. However, simplification should not lead to a reduced level of ambition, as participants called for rejections of applications for authorisations to be made easier.

Furthermore, they emphasised that the burden of proof should continue to be on the industry, in particular on the relevant actors, and the need for a better knowledge of innovative alternatives for the authorisation. Elaborating on this point, some participants acknowledged that many innovative companies are SMEs.

Participants added that it is important to receive relevant information earlier. In this regard, they suggested launching external studies or requiring downstream users to notify uses and exposures at the candidate list stage.

10.3.2.2. Diverging views

Some participants reported that they were in favour of maintaining the current authorisation process, with clarifications and simplifications, thus supporting Option 1. Some suggested that Option 1 could be considered with more fundamental changes, taking into account possible improvements presented in Option 2. However, many others expressed their preferences for merging the authorisation and restriction processes, which refers to Option 2 (on merging authorisation and restriction, as discussed below), while a few Member States had not yet been able to form a view on the three options.

In addition, a clear diverging point centred on support for the notion that “if hazardous substances can be used safely, there is no need to ban” or support for the proposition that “phasing out the substances of very high concern shall remain the driver”. Indeed, some participants emphasised that the general possibility of banning substances on the basis of their hazardous properties, which is the ‘spirit’ of the authorisation system, should be kept, maintaining that Option 2 would increase the burden of proof on Member States because of the need to demonstrate an unacceptable risk. Additionally, some participants expressed the view that in principle upstream applications are feasible, although their assessment could be difficult. For instance, they are uncertain about what is expected from the scientific assessment.

10.3.2.3. Additional points discussed

Additional issues and ideas on the specifics of the discussed option emerged during the course of this discussion. Namely, some participants said that the definition of essential uses will help simplify the authorisation process.

Participants also raised the issue of whether the problems in authorisation are fundamental. If so, it was stated that significant changes would be required.

A discussion on applications suggested that the other endpoints, for instance, those referred to in article 57, in addition to Annex XIV, should also be taken into account in applications (see the example of DEHP - di(2-ethylhexyl)phthalate). Likewise, participants recommended that substitution plans should be required in all applications.

Participants raised many other aspects to be improved such as the registration requirements, the way RMOA is conducted, confidentiality rules (which participants argue should be more flexible), and conformity checks, which should be strengthened.

Overall, participants agreed that it would be ideal to take the best of Option 1 and Option 2 (on merging authorisation and restriction, as discussed below) and merge them.
It is worth mentioning that some participants said that they were not in favour of removing the authorisation title from REACH entirely or partially.

10.3.3. Option 2: Merging authorisation and restriction

For this topic, participants were asked the following questions: What is your view on the option of merging authorisation and restriction, including giving the option to Industry to request joint derogations, along with individual derogations following the logic of the current authorisation system? Are there important elements missing? Can stakeholders envisage giving the option to Industry to jointly request derogations from restriction, with a burden of proof on Industry? Should there still be the possibility for companies to request individual derogations? Would this have the potential to render current authorisation and restriction more effective, efficient and relevant?

10.3.3.1. Common views

Participants expressed that it is important to maintain burden of proof on Industry and exert pressure on substitution, for instance, by using fees and financing, and length of derogations.

Nonetheless, participants were uncertain how this merger will work and expressed concerns that merging restriction and authorisation might increase rather than decrease complexity. This complexity lies with the difficulty in understanding how certain details will be handled. Thus, the discussion uncovered many questions among participants. For instance, there were questions on the scope of the possibility to ask for derogations (SVHC, most harmful chemicals, all restrictions?), and whether opening up the possibility for such derogations would not create too many requests. There were concerns that if restrictions were used instead of Annex XIV, whether these would be done under Article 68(1) and whether they would require Member States to prepare Annex XV dossiers. Further concerns related to the questions how to ensure that the necessary information is available at an early stage, including information on alternatives; how ECHA Committees will be involved and the basis for their evaluation. Additionally, participants agreed on the need to improve the Analysis of Alternatives.

There was a consensus that for Option 2 (like for Option 1) it was essential to find a better focus on relevant and proportionate information requirements for the application dossiers.

In addition, participants agreed that joint derogations can offer advantages and are thus potentially more efficient. However, individual derogations may still be needed for certain circumstances. There were questions about the consequences when a joint derogation is rejected and whether any fees will be involved.

Participants also agreed on the importance of timing. Information on use and exposure should be available as soon as possible and public consultations should be carried out before the assessments of the scientific committees. Any system of latest application and sunset dates should start as early as possible in the process and not lead to delays for risk management. Too wide measures could lead to enforcement issues.

While participants highlighted that this merger could be desirable, they also emphasised the need to ensure a level playing field and Risk Management Measures across companies.
10.3.3.2. Diverging views

Option 2 on merging authorisation and restriction was only supported by some of the participants. Some were uncertain and others clearly preferred keeping the two processes separate.

10.3.3.3. Additional points discussed

Participants stated that improvements (e.g., in terms of simplification) of Option 1 may be appropriate for Option 2. Furthermore, they asked how the essential use and the generic approach to risk management will affect the scope of the merged process. Additionally, participants highlighted the link to the waste and lifecycle approach.

10.3.4. Option 3: Removing the authorisation title from REACH; role of restrictions, role of the candidate list; notification obligations for uses after SVHC identification

For this topic, participants were asked the following questions: What is the initial view on the option of removing the authorisation system entirely? Should the candidate list be maintained, if so why? What could be the future role of the candidate list and what obligations should be attached to it?

10.3.4.1. Common views

Participants agreed that the current authorisation system provides a regulatory framework that requires detailed information on the uses and exposure of substance from applicants. In addition, the candidate list provides incentives for the substitution of SVHCs. A largely supported view highlighted that, in case authorisation is removed, the burden of proof would be shifted from the industry to the national authorities to demonstrate unacceptable risks, and that national authorities do not have detailed data on specific substances. In turn, this could cause a further process delay. Participants agreed that the burden of proof should remain on industry to incentivise the substitution.

Participants unanimously stated that the candidate list is an important tool under the authorisation provisions, and further considerations should be given on how it aligns with the CLP (Classification, Labelling and Packaging) Regulation (EC) No 1272/2008 and SCIP (Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD)) and on how it could be used to prioritise substances for further regulatory action.

Furthermore, participants agreed that choosing Options 3 would undermine current achievements of the authorisation system. They consider that authorisation established an important incentive in the form of a regulatory framework for substitution of SVHCs and has led to significant achievements. Efforts should therefore focus on the improvement of the current mechanism rather than on its removal. Participants added that the improvement of the authorisation process should focus on the current system development towards Option 1 or Option 2. Additionally, they discussed the consequences of the authorisation removal which should be carefully considered along with transitory measures.

10.3.4.2. Diverging views

Participants had diverging views on how to improve the current system of authorisation. The discussion between participants revolved around whether Option 1 or Option 2 are more suitable for addressing the current shortcomings of authorisation.
Some participants suggested that first it should be considered how to address the current issues under Option 1 before moving to Option 2. On the contrary, other considered Option 2 as the most suitable as it would combine the best of both systems – for instance, the burden of proof for derogations kept on the industry, restriction process and possible group derogation.

Overall, some participants stated that if Option 3 were to be considered, some key elements of the current authorisation system should be maintained – e.g., the candidate list. Regarding the future of the candidate list, one suggestion was to automatically link the candidate list to the CLP classification without the need to invest time and resources in the SVHC identification process.

10.3.4.3. Additional points discussed

Many participants emphasised that when assessing the authorisation system, it is important to analyse the number of SVHCs substituted over the past few years. The process of authorisation should thus be understood to some extent as a process of substitution.

Participants discussed that, when revising REACH, it is important to examine its alignment with other EU legislation, such as OSH and CLP in the long term and consider whether the maturity of implementation of those regulatory frameworks (e.g., OSH, IED) would allow certain risk management to be transferred from REACH to them. Finally, some participants communicated that further considerations should be given to address the alignment of the candidate list with CLP identification for endocrine disruptors.

10.3.5. Level of ambition, advantages/disadvantages of Options 1, 2, 3

For this topic, participants were asked the following questions: Without prejudice to the outcome of the impact assessment, do you have initial views on the choice between the main Options 1, 2 and 3 discussed in the morning session? What are the advantages and disadvantages of each option? Are there important considerations to be taken into account when analysing the three options (in comparison to the baseline) and their impacts?

10.3.5.1. Common views

The key points emerging from the discussion were centred around the importance of keeping the overall goals in focus, specifically substitution, the protection of health and the environment by managing the risks of remaining uses and maintaining the best of existing systems while simplifying wherever possible. Participants particularly advised ensuring that the burden of proof remains with the industry and applicants, including for authorisations and derogations from restrictions.

On this matter, participants agreed on maintaining the candidate list as a prioritisation tool for regulatory action. Participants also emphasised that both authorisation and restriction should remain regulatory instruments. Generally, most participants seemed to be in favour of Option 1 or 2 and potentially a hybrid version of the two.

10.3.5.2. Diverging views

Participants had diverging views on each of the options. On Option 1, participants stated that authorisation remains a recent approach that needs streamlining, while others doubted whether streamlining would be sufficient. On Option 2, a diverging view focused on firstly
recognising that this option has the greatest potential to improve the system, although participants questioned if it is practical and whether it will represent additional work for authorities. Regarding Option 3, participants outlined the possibility of eliminating authorisation from REACH, considering whether it can be taken over by OSH and IED legislation for example.

10.3.5.3. Additional points discussed

Additional points in the discussion suggested focusing on proportionality of the assessment rather than on burden. Participants also expressed concerns that the workload of RAC and SEAC is already stretched, and this should be taken into account in any change of the system.

Notably, some participants maintained that REACH should be an international role model and therefore only minor changes should apply.

10.3.6. National authorisations, international level playing field and export bans

For this topic, participants were asked the following questions: What are the views of participants on national authorisations as an appropriate tool to reduce the burden on ECHA and the Commission and to better take into account local conditions and preferences? What about internal Market impacts, resource needs etc.? What other ideas than those outlined in this paper do participants have to create a better level playing field, in particular for activities where regulated substances are not present in the final product? Are there considerations to be taken into account in the planned bans for exporting substances that are restricted in the EU?

10.3.7. National authorisations

Participants expressed opposition to the idea of introducing national authorisations. In this regard, they indicated that it would lead to reduced harmonisation within the Internal Market and to an increased burden for national authorities, and thus, might result in political pressure at national level. Participants stated that, in exceptional cases, such as authorisation for one Member State and one production site, well predefined and with clear criteria, such as low volume and no risk, must be ensured. Furthermore, participants asked for clarification on the link with the Industrial Emissions Directive – e.g., through a national permit based on local risk assessment.

10.3.8. International level playing field

All participants agreed on the importance of an international level playing field. Nevertheless, they raised concerns about difficulties related to its achievement. Participants stated that extending the scope of existing conventions should be considered – e.g., Prior Informed Consent Regulation, Persistent Organic Pollutants Regulation, and that cooperation within Strategic Approach to International Chemicals Management policy framework and the OECD should be further developed. Moreover, participants indicated that the sustainable product initiative could be used. They also suggested applying a certification scheme for SVHC – e.g., for imported cosmetics and to lower limit value in restriction (<0.1 %).
10.3.9. Export bans

Regarding export bans, participants were in favour of including manufacturing in the authorisation procedure. At the same time, international fora should be used to encourage adoption of similar rules internationally – e.g., through extending the scope of existing conventions. The approach of the Basel Convention on the export of waste should be explored for SVHCs listed under REACH.

Overall, participants advised establishing a EU trace policy as well as environmental standards of export and import of SVHC.

10.3.10. Interface REACH-other EU legislation

For this topic, participants were asked the following questions: Would a stronger integration of regulating workplace-related risks create value added compared to the current situation? What aspects are to be considered? Should stronger integration imply transfers of legislative tasks (i.e., certain BOELs from OSH to REACH, or all worker protection measures from REACH to OSH)? Which route should be preferred? What are the elements that an impact assessment on such options should be considered? Are there additional options? Should there be a stronger integration of measures with permitting under the Industrial Emissions Directive? Are there interfaces with other EU legislation which should be assessed as a priority?

10.3.10.1. Common views

Even though the subject was not discussed in detail, most participants agreed that REACH-OSH is the most important interface. Stronger integration could provide an added value, and both systems could be complementary and thus avoid work duplication. However, legal consequences and implications for companies should be carefully analysed.

During the discussion, participants agreed that while both systems have their own merits and different scopes (e.g., process generated substances are covered only by the OSH legislation), the goals for combined impacts of the two regimes must be coherent, effective and proportionate. To do so, clear criteria to determine the most appropriate regulatory routes must be ensured along with safeguarding the involvement of social partners. Additionally, the participants also drew attention to the need to support the transfer of legislative regulatory tasks.

Participants considered RMOA to be of utmost importance in decision making, which could also bring REACH-OSH experts together. Most participants were in favour of harmonising limit values to prevent divergence.

In line with the common views on the REACH-OSH interface, participants stated that this interface will lead to regulatory conflicts not only with restrictions but also with authorisation. Finally, participants agreed on the necessity of holding joint REACH-OSH higher level discussions – e.g., using CARACAL or ACSH.

There was only a slight divergence of opinion on whether the harmonisation of limit values is actually necessary.
10.3.10.2. Additional points discussed

Regarding the other interfaces with REACH, participants exchanged views on the IED, Cosmetics, Batteries, Waste, RoHS (Restriction of Hazardous Substances), toys, POPs, Oslo-Paris Convention (on marine environment), Green Deal, Zero Pollution ambition and Circular economy.

Additionally, REACH experts from many Member States were not aware of the current discussion on the Batteries Regulation and its restriction of chemicals. They all agreed on the principle of 'one substance, one assessment', and that there can be different legislative acts to deal with each assessment. The importance of determining DNEL with CLP legislation was also mentioned.

10.3.11. Innovation and how to support substitution; improving enforceability and impact on SMEs

For this topic, participants were asked the following questions: What is your view on the use of financial instruments to incentivise substitution at EU level? How could such financial instruments be designed? Are there any other ideas to promote innovation and substitution under REACH? What is the view on giving the Forum a similar role as RAC and SEAC? What measures can be taken to accommodate specific constraints of SMEs?

10.3.11.1. Common views

Participants agreed on the importance of strengthening incentives for substitution. They also agreed on increasing the role of the Forum, which should be more involved in later stages since a restriction proposal typically changes during the opinion process. Moreover, participants indicated that the Forum’s role in authorisations should be considered.

Overall, participants addressed the question of innovation and means to support substitution. During this exchange, participants insisted on the need to strengthen incentives for innovation and substitution, and they advised that a one-way financial instrument should be created. Another topic discussed was the impact on SMEs, although it was not covered in detail. Participants emphasised the need to provide more information on alternatives that can help SMEs.

10.3.11.2. Diverging views

Participants had diverging views on two points: the use of financial instruments and the role of the Forum.

Regarding the first point, some participants suggested that the use of financial instruments provides an incentive, but other participants argued it represents an additional burden on the industry. In addition, some participants pointed out that such an instrument could create a level playing field between forerunners that are investing in innovation and reluctant actors in regards to substitution. To create a level playing field, the IED process was mentioned as a way forward to build a common expertise with sector-specific area. Nevertheless, it may also cause an issue regarding the international level playing field if only EU companies are obliged to pay such a fee/tax. Overall, the use of financial instruments would require further assessment – for example, the criteria for the level of fee/tax and how and for what purpose it will be used (funding R&D activities, industrial
scaling-up, enforcement actions). It was noted by some participants that funding of R&D activities has, however, not been efficient.

On the second point, some participants emphasised the importance of clarifying the role of the Forum, which should ultimately not be a formal one similar to the roles played by RAC and SEAC. Additionally, it should not delay the decision process. Overall, participants added that the issue of enforceability can be about standardisation of methods for chemicals analysis, which is more an issue for standardisation committees.

10.3.11.3. Additional points discussed

Participants discussed the question of providing more information about alternatives prior to a substance being placed on the authorisation list — e.g., by launching an independent study on alternatives and including a wide industry consultation aiming to obtain as much information as possible. Participants discussed the opportunity of the additional use of national workshops for industry sectors where both providers of alternatives and the users are involved.
### List of abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>ACSH</td>
<td>Advisory Committee for Safety and Health at Work</td>
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<td>AoA</td>
<td>Analysis of Alternatives</td>
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<tr>
<td>CARACAL</td>
<td>Competent Authorities for REACH and CLP</td>
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<tr>
<td>CLP</td>
<td>Classification, Labelling and Packaging) Regulation (EC) No 1272/2008</td>
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<td>DEHP</td>
<td>Di(2-ethylhexyl) phthalate</td>
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<td>DUs</td>
<td>Downstream users</td>
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<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
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<td>ED</td>
<td>Endocrine disruptors</td>
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<tr>
<td>Forum</td>
<td>Forum for Exchange of Information on Enforcement</td>
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<td>IED</td>
<td>Industrial Emissions Directive 2010/75/EU</td>
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<td>NPE</td>
<td>Nonylphenol ethoxylates</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<tr>
<td>OPE</td>
<td>Octylphenol ethoxylates</td>
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<tr>
<td>OSH</td>
<td>Occupational Safety and Health legislation</td>
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<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
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<td>PIC</td>
<td>Prior Informed Consent Regulation</td>
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<td>POPs</td>
<td>Persistent Organic Pollutants Regulation</td>
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<tr>
<td>R&amp;D</td>
<td>Research &amp; Development</td>
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<tr>
<td>RAC</td>
<td>Committee for Risk Assessment</td>
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<td>REACH</td>
<td>Registration, Evaluation, Authorisation and Restriction of Chemicals</td>
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<td>RMM</td>
<td>Risk Management Measures</td>
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<td>RMOA</td>
<td>Risk Management Option Analysis</td>
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<td>RoHS</td>
<td>Restriction of Hazardous Substances</td>
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<tr>
<td>SAICM</td>
<td>Strategic Approach to International Chemicals Management policy framework</td>
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<td>SCIP</td>
<td>Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive</td>
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<td>SEAC</td>
<td>Committee for Socio-economic Analysis</td>
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<tr>
<td>SMEs</td>
<td>Small and medium-sized enterprises</td>
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<tr>
<td>SVHCs</td>
<td>Substances of Very High Concern</td>
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11.1. Executive summary

The European Commission held a workshop on the reform of REACH Authorisation and Restriction in Brussels (Belgium) and online simultaneously on 12 November 2021.

The workshop was organised in the context of the planned reform of the REACH authorisation and restriction system based on the 2018 REACH Review and as announced in the Chemicals Strategy for Sustainability. The planned reform aims to build on positive experiences of implementing the REACH authorisation and restriction processes, while addressing current weaknesses and inefficiencies.

The workshop aimed to inform stakeholders of the initial thinking of the Commission’s services on the planned reform of the REACH authorisation and restriction system, as well as other elements that will be included in the impact assessment. The workshop was also an opportunity for stakeholders to give their initial reactions, helping to refine the policy options and inform the Commission’s impact assessment.

The workshop comprised two plenary-informative sessions, along with interactive world- café sessions that allowed participants to provide feedback to the questions concerning the options and elements addressed in the impact assessment. Participants were assigned to one of eight ‘world café’ tables for the discussion of eight topics. The key points of the interactive world café tables were reported in the plenary session as per subject matter. The key elements discussed in the interactive sessions concerned (i) problem analysis and objectives of the reform, (ii) three defined policy options under scrutiny of the REACH revision (three separate discussions, each one dedicated to one option), (iii) level of ambition, advantages and disadvantages of each policy option, (iv) national authorisations, international level playing field and export bans, (v) interface REACH – other legislation, (vi) innovation and how to support substitution, improving enforceability and impact on SMEs. Summaries from these group discussions are presented in this report.

Problem analysis and objectives of the reform

A general consensus among the participants was reached on the need to revise the current authorisation and restriction processes. One of the key problems raised by participants was that inefficiency of the current system of authorisation and restriction which in part was due to burdensome procedures and the dependence on applicant’s data for assessment. Participants pointed out that the policy options proposed by the Commission’s services could be further detailed and an explanation of how they will address the identified problems of the authorisation/restriction process should be provided.

The reform should allow for legal certainty for industry stakeholders on granted authorisation, their duration and review processes. Industry representatives emphasised the impact of authorisation on EU competitiveness vis-à-vis imported articles or substances. Burdensome procedures can cause level playing field issues between EU and non-EU companies.

Participants were divided on the ultimate objectives of the reform. While some stakeholders claimed that the reform process should lead to an increased rate of substitution of substances of very high concern in the EU market, some considered that it should focus on improving the management of risk. Therefore, a clearer definition of the objectives of the reform would be needed.

Discussion around policy options

To better structure the impact assessment, the Commission has identified four main options, including the baseline option:

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Option 3: Remove the authorisation title from REACH; role of restrictions, role of the candidate list; notification obligations for uses after SVHC identification.

The abovementioned options help assess the overall degree to which the authorisation and restrictions system should be reformed and are fundamental to determining the extent of the planned reform. The proposed options were designed from the point of view of authorisation since there is a higher need to reform the authorisation system, whereas the main elements of the restriction system can remain in place. During the workshop, Options 1, 2 and 3 were discussed in more detail with participants.

Participants did not express clear preferences in terms of proposed options for the REACH reform of authorisations and restrictions. Most participants recognised the merits of the authorisation system and considered the removal of authorisation (Option 3) as radical and not preferable. It was pointed out that authorisation and restriction systems are complementary and each of them has its own merit.

Despite the absence of a clearly preferred option, many participants argued that Option 1 would be the easiest and most certain solution for the ongoing reform, even though the scope of Option 1 could be improved. For instance, objectives and functions of the candidate list could be further defined, while sectoral specificities could be considered to some extent when improving the authorisation process.

Concerning Option 2, participants agreed that, if this option were to be selected, simplification of the current authorisation process should be an important objective. Some participants emphasised that merging authorisation and restriction may not actually lead to the desired reduction of administrative burden — neither on the side of Member States nor on the industry side — and some saw the risk of creating a more complex rather than a simpler system.

Participants agreed that the discussion revolved around very high-level descriptions of the options and further details should be provided, especially with regards to a broader context of other parallel considerations such as for the generic approach to risk management and essential uses. The Commission therefore must take into account some important considerations when tailoring the options, such as the need to clearly define the goal of the new reform process, along with the efficiency of the options, their enforceability and their coherence with other pieces of legislation.

National authorisations, international level playing field and export bans

Most participants were not in favour of the involvement of national authorisations, arguing that this would lead to diminished harmonisation across the EU, the fragmentation of the internal market, increased administrative burden for national authorities and the risk of additional political pressure at national level. However, some participants noted that SMEs could potentially benefit from national authorisations as these could result in lower costs and faster procedures.

Participants also support an international level playing field while recognising certain difficulties that could arise from its implementation. Several ideas were proposed for creating such a level playing field, such as the extending existing international conventions on restriction of chemical substances. Other proposals included learning from climate discussions on carbon border adjustment mechanisms; introducing a certification scheme for substance of very high concern similar to China's cosmetics regulation; and reducing requirements for EU companies when the substance used only in the process complies with the requirements of Occupational Safety and Health legislation and Industrial Emission Directive.
Finally, participants did not reach clear agreement on the implementation of export bans. Some were in favour and pointed out that, even if it is hard to act outside the EU, the bloc must remain a frontrunner, setting an example to third countries. However, most participants were rather critical, noting that multinational companies could produce the substances in different regions of the globe and that the EU cannot stop the use of the substance in third world countries. It was noted that, in general, value chains are complex, and export bans could be detrimental since substances could be restricted for a totally different use in EU than the one outside EU. Participants proposed to use international fora and to extend the scope of existing conventions. It was suggested that the approach used in Basel convention (export of waste) is explored, as well as the setting of an environment standards for the export and import of SVHC.

Interface REACH – other legislation

The most important interface discussed was between REACH and the Occupational Safety and Health Directive. Most participants considered that the OSH Directive and REACH Regulation should remain separate. It was argued that OSH should be the main legislation to cover workers’ protection, while REACH should complement this protection where necessary – e.g. for consumer uses. The interface between the two legislations, however, still has room for improvement.

Participants also recognised the need to further improve the interface of REACH with other EU legislation to ensure coherence and synergies between these instruments. The other key pieces of legislation identified under this subject were the Industrial Emissions Directive, the Batteries Directive, the Waste Framework Directive, the Water Framework Directive, legislation on plant protection products, the Biocidal Products Regulation, the Toy Safety Directive, the Regulation on Cosmetic Products and food contact materials legislation.

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

Most participants agreed that innovation and research and development are important elements for substitution of SVHCs under REACH. Although the current system already provides an incentive for substitution, participants emphasised that substitution is a complex process and particularly challenging for SMEs. Stakeholders had diverging views on whether the authorisation process is burdensome and whether it blocks innovation for companies rather than favouring innovation and substitution.

11.2. Introduction

11.2.1. General context and objective of the workshop

The European Commission held a workshop on the reform of REACH Authorisation and Restriction in Brussels (Belgium) and online simultaneously on 12 November 2021.

The workshop focused on the planned reform of the REACH authorisation and restriction system announced in the Chemicals Strategy for Sustainability. The agenda and background document of the workshop are added as annexes at the end of this report.
The policy options to revise authorisations and restrictions in the REACH Regulation, which are considered by the Commission, aim to:

- free resources to tackle a wider range of more relevant chemical risks;
- make the authorisation and restrictions processes more efficient and effective;
- achieve a higher level of protection of human health and the environment from the risks of the most harmful substances; and
- give clearer signals and more planning security to companies.

The main policy options considered are the following:

- Option 1: keep authorisation provisions with clarifications and simplifications
- Option 2: merge authorisation and restriction provisions
- Option 3: remove the authorisation title from REACH

In the above context, the main objectives of the workshop of 12 November 2021 were to inform and familiarise stakeholders with the initial thinking of the Commission services on the planned reform of the REACH authorisation and restriction system, as well as other elements that will be assessed in the impact assessment. It was also intended to get initial reactions from stakeholders, helping to refine the policy options and to inform the Commission's impact assessment.

A similar workshop with Member States was held on 9 November 2021. The two workshops are part of wider consultations on the reform of the authorisation and restrictions processes. The discussion will continue in CARACAL meetings in January and March 2022, and others may follow, as necessary.

As part of the wider consultations planned for the impact assessment of the revision of the REACH Regulation, a public consultation will be launched (tentatively from December 2021 until March 2022), as well as targeted consultations in the form of questionnaires and follow-up interviews. Several contractors are supporting the Commission with the impact assessments. For the revision of authorisation and restriction under REACH, a specific study is being carried out by a consortium of consultancies (VVA Consortium).

11.2.2. Workshop organisation

The workshop was held in a hybrid format. Some stakeholders participated offline at the European Commission's premises while others participated online, via a virtual connection. The agenda of the workshop is presented in Annex 1 of this report.

The Commission invited the stakeholders to provide feedback to the questions presented in the background document (Annex 2) during the 'world café' table discussions. Participants were allocated to one of eight tables with every table allotted 30 minutes to discuss each of the topics. A moderator and a rapporteur were allocated to each of the eight subjects on the different tables. A summary of discussions was reported back to the plenary session. While the opening and closing sessions of this workshop were streamed online and made accessible to any registered participant, the world café tables were accessible only to the participants of that table.

After the opening session, two rounds of the world café tables were organised, each running for two hours. The first round took place in the morning and the second round in the afternoon.
Topics discussed during the morning session of the world café tables:

- Problem analysis and objectives
- Option 1: Elements for simplification of the current authorisation system
- Option 2: Merging authorisation and restriction
- Option 3: Removing the authorisation title from REACH; role of restrictions, role of the candidate list; notification obligations for uses after SVHC identification

Topics discussed during the afternoon session:

- Level of ambition, advantages/disadvantages of options 1, 2, 3;
- National authorisations, international level playing field and export bans;
- Interface REACH-other EU legislation, and
- Innovation and how to support substitution, improving enforceability and impact on SMEs.

The last part of the workshop focused on feedback from the participants on the eight topics discussed. A summary of the discussions per topic was presented by rapporteurs of the world café tables.

Finally, the participants were invited to submit their written contributions to the Commission by email (GROW-ENV-REACH-REVISION@ec.europa.eu) and to contribute to the Open Public Consultation, which is tentatively planned to run from December 2021 until March 2022. Furthermore, participants are welcome to provide answers to a questionnaire prepared as part of the targeted consultation on the reform of authorisation and restriction which may be followed up by individual interviews with stakeholders.

11.2.3. Participants

In total, 75 stakeholders registered to participate actively in the discussions (37 in person and 38 online) at the workshop. Additionally, 260 stakeholders registered to listen online to the opening and feedback sessions.

Various organisations were represented in the workshop: trade unions, industry associations, companies, NGOs, law firms, consultancies and government agencies. The sectors of industry represented included: minerals and metals; chemicals; automotive; healthcare; plastics and silicons; cleaning products; aerospace; batteries; petrol; textiles and fibres; paint and printing inks, and solar. The graph below presents the number of stakeholders per type of organisation, represented in the workshop.
11.3. World Café Tables

This section presents the key points that emerged from the discussions on each of the eight topics and summarises them by 1) common views, 2) diverging views and 3) additional points discussed among participants.

A background document was sent to the workshop participants (see Annex 2 of this report) to present the main issues of the REACH regulation’s authorisation and restriction process, as identified by several documents such as the Commission’s inception impact
11.3.1. Problem analysis and objectives

For this World Café Table, participants were asked the following questions: What is your view on the Commission’s initial analysis of underlying drivers, in particular the analysis of the implementation of the current REACH authorisation and restriction processes and their achievements, problems and deficiencies? Are there missing elements?

11.3.2. Common views

Most workshop participants agreed that the background document of the Commission provided a good description of the problems and challenges to how the REACH authorisation and restriction processes are currently working. It was also unanimously agreed that a revision of REACH was needed.

However, many stakeholders highlighted that some elements were missing from the problem analysis and that some issues could be further addressed. For example, it appeared not clear how the options presented would solve the identified problems. Also, many stakeholders highlighted that the problem analysis could take a broader perspective and include clear links with the objectives of the European Green Deal.

During the discussions, it was also emphasised that the relationship between REACH and sectoral legislations could be better described (e.g. regarding sectoral approvals). Challenges around imported articles under authorisation could also be further highlighted, as this can have an important impact on the level playing field between EU and non-EU companies.

Additionally, the issue of the overall efficiency of the authorisation and restriction processes was raised. For most participants, the problems due to slowness of the authorisation and restriction processes were not stressed sufficiently in the problem analysis.

Still relating to the authorisation process, stakeholders emphasised the importance of legal certainty in the process in terms of granted authorisation or not, but also in terms of review period and duration of this process.

Finally, according to most participants, not enough emphasis is placed on the burden of the authorisation and restriction procedures on the SMEs. It is not only the application for authorisation that can be burdensome for SMEs, but also the compliance with the authorisation and restriction decisions. Some participants were of the view that this may ultimately hamper investment in innovation.

26 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-

28 Notably the latest ECHA’s study, “Causal impacts of the REACH Authorisation process on the use of substances of very high concern in the EU”, ECHA, 2021 (forthcoming)
11.3.3. Diverging views

Participants disagreed on some of the problems related to authorisations and restrictions and objectives of the reform. For example, it was not clear to participants what should be the overall objective of the new REACH Regulation. Some stakeholders suggested it should drive substitution, while others argued that emphasis should be placed on risk management. The definition of clear objectives would be welcomed as it would affect how the legislation is designed.

Another missing challenge concerned the authorisation, and whether it can slow down the substitution of substances to some extent. On the one hand, industry representatives thought that the authorisation process is too burdensome. As a result, resources that could be invested into research and development are instead spent on the application for authorisation, hence blocking innovation. On the other hand, NGOs' representatives disagreed, highlighting that it is the purpose of the authorisation process is to incentivise the substitution of substances.

Some of the stakeholders mentioned that the inefficiency of the authorisation system may be linked to a too high dependency on applicants' data for the assessment of the application to authorisation. As soon as the data provided by the industry is not complete or not relevant, the whole application process is blocked. On this point, NGOs were of the opinion that the process should move forward even if not all the data needed is available, while industry representatives highlighted that the risk management approach should remain based on evidence and that Risk Management Measures (RMM) cannot be taken without sufficient data. Stakeholders also disagreed on the role and importance of Risk Management Options Analyses to choose the right process from the beginning.

11.3.4. Additional points discussed

Further points raised by participants included concern about the loss of performance for alternatives, since it is hard to define what is an acceptable performance and who is empowered to decide on that matter.

Additionally, several industry representatives emphasised that the diversity of industry as well as the complexity of the value chains should be taken into account in the problem analysis. They suggested that a more sectoral approach should be adopted when revising the REACH authorisation and restriction process, as this would enable the specifics of the different sectors to be taken into account. Furthermore, other industry representatives highlighted that the time allocated for the industry to react to the authorisation/restriction process is too scarce in view of the important time needed for innovation and R&D.

Finally, stakeholders pointed out other elements that could be considered during the revision of REACH, such as the development of transitional arrangements, and the careful setting out of conditions for use under the authorisation process.

11.3.5. Option 1: Elements for simplification under the current authorisation system

For this World Café Table, participants were asked the following questions: What is your view on the Commission's initial collection of elements for simplification of the current authorisation and restriction systems? Are important elements missing? To what extent would addressing those elements be sufficient to remedy the observed problems with authorisation and restriction?
11.3.5.1. Common views

Most stakeholders considered that both the authorisation and restriction process should continue to exist. In this view, Option 1 could be considered, with room for improvements such as the introduction of legal changes and a focus on essential uses. Additionally, the sectoral specificities could be taken into account to improve the processes. This would also imply a stronger cooperation between actors in the process.

Simplifications should be made on issues such as small quantities, processes with very low exposure or emission levels, R&D exemption and strictly controlled conditions, as well as on the scope of substances targeted (which could be refined) and sectoral specificities. It appeared to be important for all stakeholders that the intended simplifications do not eventually make the process more complex. Simplifications would be particularly required for SMEs, as the current system can be very costly and burdensome for them, and they can experience difficulties in providing data.

A key message from the stakeholders was the need to stress the importance of obtaining the relevant information, particularly on uses, at an earlier stage than is currently the case. Improved knowledge of alternatives, use and exposure, for instance at the candidate list stage, are also needed. This could mainly improve predictability for the relevant industries. It was suggested to introduce data sharing obligations in the application phase, similarly to the current registration process.

Several industry representatives highlighted the need to target the use in the authorisation process in order to improve the proposed clarifications. Therefore, substitutions should be more targeted on the uses. Stakeholders also argued that more focus should be put on the alternatives, even though there are still some uses where no substitution is possible. Finally, industry suggested making Regulatory Management Option Analysis (RMOA) mandatory.

As another example of simplification, several stakeholders argued that the assessment of alternatives could be improved by taking all possible impacts into account, such as performance and energy consumption.

Finally, it was highlighted that downstream users have a detailed knowledge of the processes and how the chemical substances are used. They can therefore also provide information on uses and their engagement in the process is thus vital. Strengthened cooperation with other actors of the supply chain and authorities would also be important for successful reform.

11.3.5.2. Diverging views

Overall, the participants had very few diverging views on option 1. Nevertheless, some stakeholders argued that they did not see the added value of the option, as for some industries, authorisations do not grant the planning certainty that would be needed. One stakeholder suggested removing the authorisation process as a whole.

Participants had diverging views on the extent to which substitution for the sake of substitution should be the goal in the REACH process, in comparison to exposure reduction.

An important point of divergence arose between stakeholders on the route to follow for granting an authorisation. On the one hand, NGOs highlighted that it would be relevant to implement only one route, the adequate control route, where risk must be proven to be minimised. This route should also include a credible substitution plan presenting how much time would be needed to implement the change, while the socio-economic assessment would be removed. On the other hand, industry representatives argued that the socio-economic assessment brings proportionality to the debate, and that there should be an assessment considering all the possible dimensions.
In addition to the above points, stakeholders highlighted that the definition of some terms could impact and simplify the REACH authorisation process. This includes the definition of essential and non-essential uses, sub-uses, intermediates, and the definition of what could be considered economically feasible.

Furthermore, some stakeholders suggested that a more important role should be given to the candidate list and to the substitution plan during the application process. Some even suggested that the substitution plan should be binding, meaning that it would be part of the authorisation decision and would have a legal status. Applicants could thus be legally challenged if their substitution plan is not complied with. Additionally, it was mentioned that this substitution plan could play an essential part in the promotion of innovation and it could encourage companies to provide a comprehensive analysis of the substitution activities. Regarding the candidate list, several stakeholders added that it could trigger the provision of information from the users. This could provide more time to explore alternatives and see where the uses are. Also, fees for the use of SVHCs could be introduced.

Some stakeholders, including mainly NGOs, asked for additional clarification elements to be integrated in option 1. Clarifications could be provided on how to tackle the issue of high dependency on the applicants’ data. Furthermore, the issue of multiple applications for relatively simple cases could also be considered. Several stakeholders have also highlighted that it should be possible to allow a parallel placement of substances on Annex XIV and XVII simultaneously.

Several points were discussed in relation to the Occupational Safety and Health (OSH) Directive. It was argued that the link between workers’ legislation and the REACH process should be improved in the current authorisation system, for instance with conditions or industry hygiene campaigns. Another potential simplification to be considered is to remove process chemicals from the authorisation process and place them under OSH.

Finally, few industry representatives pointed out the lack of guidance from the authorities on the upstream applications as an issue to be tackled. They also argued that more information on the different steps of the authorisation process should be made available to provide a common understanding of how the process works.

11.3.6. Option 2: Merging authorisation and restriction

For this World Café Table, participants were asked the following questions: What is your view on the option of merging authorisation and restriction, including giving industry the option to request joint derogations, along with individual derogations following the logic of the current authorisation system? Are there important elements missing? Can stakeholders envisage giving industry the option to jointly request derogations from restriction, with a burden of proof on industry? Should there still be the possibility for companies to request individual derogations? Would this bear the potential to render current authorisation and restriction more effective, efficient and relevant?

11.3.6.1. Common views

Participants agreed that if Option 2 were to be selected, simplification proposals of current procedure should be considered. They also agreed that merging authorisation and restriction as described in Option 2 may not lead to a reduced administrative burden for Member States or for companies.

One of the solutions envisaged to reduce the burden of applications, namely the joint application system, was not considered as having the ability to fulfil that goal due to
confidentiality as well as competition law issues. Moreover, even if these two hurdles were to be overcome, the question of the degree of detail required for the application would remain. This unresolved question could cause a joint application to be a group of very detailed individual applications. Finally, joint applications should not lower the pressure for substitution of substances.

Another point raised and agreed upon was the necessity for Option 2 to consider the links with other sectorial legislation, especially regarding how the control of emissions is handled.

Moreover, all participants agreed that the candidate list is a good element of the REACH Regulation and that it should be maintained. Regarding substances that should be targeted in Option 2, two additional points were made:

- Firstly, the proportionality of effort is a key issue and substances should be targeted as a function of their impact. This would allow focus to be placed on resources on the most problematic substances with the biggest uses. Consequently, resources would not be wasted on applications and evaluations for substances with very limited negative impacts.
- Secondly, there needs to be a special focus on process chemicals which are used in the manufacturing of goods but not present in the end product, to ensure that European companies do not lose a competitive advantage vis-à-vis third countries that are not subject to the same legislation.

Finally, it was noted that the timing for information provision, assessment of derogation applications, and the transition period between the current system and the next one are key aspects for the industry. It must be able to adapt and transition smoothly so as to not lose access to specialty substances required for their manufacturing processes or end products.

11.3.6.2. Diverging views

Participants had diverging opinions on various aspects of Option 2, the first of which concerned whether Member States or the industry should bear the burden of proof. This issue was raised consistently by NGO representatives arguing in favour of putting the burden on the industry, with industry representatives arguing for the opposite (putting the burden of proof on Member States).

Regarding the basis for targeting substances with the legislation, participants disagreed on the approach to be used. Some participants were concerned that by implementing Option 2, there would be a shift from a risk-based approach to a hazard-based one, highlighting that hazard would always be there and that it could not be removed entirely, and that the legislation should focus on addressing “unacceptable risk”.

11.3.6.3. Additional points discussed

One participant deplored the impossibility to legally challenge a restriction.

Additionally, some elements were discussed that do not necessarily concern Option 2 but rather improvements to the REACH Regulation. The following were recommended:

- the most appropriate regulatory options for each use of a substance should be chosen at the beginning of the process and the RMOAs could serve this purpose;
- the OSH regulatory practices should be improved and their harmonisation could be a relevant approach to do so; and
- the enforcement of the revised REACH Regulation will be challenging and must be carefully thought through.
11.3.7. Option 3: Removing the authorisation title from REACH; role of restrictions, role of the candidate list; notification obligations for uses after SVHC identification

For this World Café Table, participants were asked the following questions: What is your initial view on the option of removing the authorisation system entirely? Should the candidate list be maintained, and if so, why? What could be the future role of the candidate list and what obligations should be attached to it?

11.3.7.1. Common views

Most stakeholders recognised the merits of the authorisation system and considered the removal of authorisation as a radical and not desired option. It was highlighted that authorisation and restriction systems are complementary in substance. However, while it is not desirable to remove the authorisation system, most of the stakeholders emphasised the current shortcomings of authorisation and that there is clear room for its improvement during the reform process.

Thus, according to stakeholders, the removal of the authorisation discussed under Option 3, must be considered in the broader picture, not only in terms of REACH but also in terms of other pieces of relevant legislation (e.g. OSH IED) and their respective revisions. During the discussion on the removal of authorisation, the majority of stakeholders pointed out that, if considered, such removal would require a careful reflection on which elements of authorisation work well and therefore need to be maintained.

Stakeholders agreed that the system in place provides for important regulatory certainty as regards the procedures in place. Also, the system provides for a well-functioning internal market. In this context, many stakeholders expressed their concern regarding the future possibility of submitting requests for derogation under restrictions in case Option 3 were to be selected.

The removal of authorisation considered under Option 3 may cause a legal vacuum regarding the existing procedures. The industry representatives emphasised that important work has been undertaken on their side to comply with the current authorisation system. Therefore, the switch to the new model would require new time-consuming alignment and investment.

Finally, it has been highlighted by most stakeholders that the authorisation system, together with its candidate list, constitutes an important incentive for substitution of SVHCs for the industry stakeholders. Also, the candidate list is perceived as an informative tool, indicating where future regulatory action could take place. Nevertheless, several stakeholders pointed out that it should be further considered how the list exerts its role. Indeed, the procedure around the establishment of the candidate list seemed unclear to some stakeholders.

11.3.7.2. Diverging views

The discussion did not bring many diverging points. However, the stakeholders did not fully agree on what should be the objectives and procedure of the candidate list. While for some stakeholders the candidate list represents a very useful and informative tool allowing for identification of possible foreseeable regulatory areas as regards SVHCs, for others it is considered a redundant and resource-intensive instrument.
Finally, concerns were raised regarding the future scope of the candidate list. While some of the participants supported a *more inclusive and long list* (including the scope of substance under SPI, the Chemicals Strategy for Sustainability and the ongoing Roadmap, etc.), some others considered such a long list as an unhelpful tool and voiced their preference for a *short or prioritised list*.

### 11.3.7.3. Additional points discussed

Additionally, many industry stakeholders expressed their concerns about the current system’s *legal uncertainty over the use of specific substances*. According to many industry representatives, the industry *needs more clarity and predictability of RMG conclusions* regarding the authorisation regime. It has been suggested that the burden of the derogation process should be proportionate when addressing tonnage or usage of substances. The current one-size-fits-all does not seem always adequate.

Moreover, the *coherence between the candidate list of REACH and other pieces of legislation* (other existing tools) relevant for chemicals should be ensured, as well as aligned with “one substance-one assessment” approach. On this point, some stakeholders questioned whether substances for which an Operational Exposure Limit (OEL) is available should remain on the candidate list.

Finally, some stakeholders suggested that the current system should envisage the *possibility of challenging the authorisation and restriction decisions* by giving the industry stakeholders the possibility to appeal.

### 11.3.8. Level of ambition, advantages/disadvantages of options 1, 2, 3

For this World Café Table, participants were asked the following questions: *Without prejudice to the outcome of the impact assessment, do you have initial views on the choice between the main options 1, 2 and 3 discussed in the morning session? What are the advantages and disadvantages of each option? Are there important considerations to be taken into account when analysing the three options (in comparison to the baseline) and their impacts?*

#### 11.3.8.1. Common views

Stakeholders *did not have a clear preferred policy option* for the REACH reform, notably due to the level information provided so far on these options being too high. The options could be further developed, and it could be more clearly indicated how they fit into other ongoing debates on the generic approach to risk management and essential uses. However, some tendencies emerged with regards to the choice of option.

**Option 1** (with some modifications) was supported by several NGOs and Industry representatives. One of the most claimed reasons for support for this option was the fact that it deviates least from the current situation thus the effects of changes could be the most predictable. In addition, all of options it was expected to be the easiest one to adapt to. Limitations and disadvantages identified for Option 1 included the fact that the simplification elements proposed have already been attempted in recent years, without clear success as real changes would have required the revision of the REACH Regulation. In addition, it was claimed that Option 1 does not take sufficiently into account the high dependency on applicant’s data during the application for authorisation. Also, it does not take into account the multiple and smaller applications for authorisation nor does it address the weaknesses
of the restriction process – i.e., the fact that the burden is on authorities. For this latter aspect, it was proposed that for substances targeted for RMOA, the industry prepares a risk assessment. This would imply a “RMOA-list” under REACH with a burden of proof on the industry to prepare the risk assessment. If there are risks identified, the substance would be submitted to authorisation. Even though option 1 was considered as the most interesting option, the stakeholders stressed that it should still be revised and improved.

Industry representatives also considered Option 2 to be promising since it could be a good alternative for downstream users, who do not have knowledge or resources to prepare applications for authorisation under the current system. Another positive element of this option was that a request for derogation from a generic restriction be made, the burden of proof is on industry. Overall, however, the option was considered too uncertain, with an unclear scope (e.g., type of use, specific material), possibly rendering the authorisation process more complex than the current one. Were this option to be adopted, industry indicated that it would need clarity on the level of proof required (e.g., equal level of protection) for derogation requests.

Finally, there was a broad consensus on Option 3, which was considered as being not viable and too radical.

Regardless of the specific option ultimately implemented, all participants agreed that the following aspects need to be ensured:

- a clear definition of the goal of the new rules
- proportionality, with a focus on elements that have the greatest impact
- predictability for stakeholders (via earlier information collection)
- efficiency in order to deliver outcomes faster
- enforceability
- coherence with other EU legislation

Other elements that found broad support were the acknowledgement of the importance of the candidate list as a tool to prompt substitution. In addition, there was a general request to provide information early in the process notably on uses, volumes, alternatives, and market analysis. Also, the objective should be set out upfront, and the right regulatory action should be selected based on this aim. RMOA should play a more important role (but should not delay the process). Overall, it was agreed that earlier information collection would be beneficial for the authorisation process, while at the same time increasing predictability for industry.

Finally, it was remarked that in all simplification efforts care must be taken to avoid creating a system that is more complex than the one in place today.

No specific diverging views emerged during this discussion.

11.3.8.2. Additional points discussed

A few additional points were raised by the stakeholders during the discussions on the options for reform. For example, several industry representatives emphasised that a unique solution to simplify the REACH authorisation and restriction system would be difficult to find for the industry, because the industry landscape is not homogeneous, and there may be specific issues in specific sectors. Stakeholders also mentioned that,
when clarifying the authorisation system (Option 1), attention should be paid to the essential use concept, the definition of loss of performance and substitution plan. Improved coordination between actors taking part in the authorisation and restriction system would also be important. Furthermore, regardless of the concrete option ultimately implemented, stakeholders indicated that sufficient capacity should be available at the level of authorities.

Finally, several NGOs added that in Option 2, fees for users and manufacturers of candidate-listed chemicals could be introduced, as well as fees for derogation requests. An NGO also proposed to make substitution plans mandatory for all applications.

11.3.9. National authorisations, international level playing field and export bans

For this World Café Table, participants were asked the following questions: What are your views of participants on national authorisations as an appropriate tool for reducing the burden on ECHA and the Commission, and to better take into account local conditions and preferences? What about internal market impacts, resource needs etc.? What other ideas than those outlined in this paper do participants have to create a better level playing field, in particular for activities where regulated substances are not present in the final product? Are there considerations to be taken into account on the planned bans for exporting substances that are restricted in the EU?

11.3.9.1. National authorisations

Overall, a significant majority of the participants in the workshop were sceptical about the practicabilities of national authorisations. They mentioned many challenges of a system in which national authorisations replace or complement the EU authorisations. For instance, participants mentioned the danger of creating incentives for Member States to lower protection standards to attract businesses. Reduced protection levels in some parts of the EU reduces harmonisation and leads to the fragmentation of internal market. Also, participants mentioned the danger of having different authorisations processes, which multiplies the requirements for companies that work in more than one Member State.

Additionally, participants mentioned that national authorisations could be even more prone to political pressures to favour national champions. Such an outcome would undermine the protection levels in the EU. However, participants also questioned whether national authorities has sufficient resources for managing national authorisations. A lack of resources could even increase the time needed for the procedures, thus increasing the administrative burden for national authorities.

Another key challenge mentioned by participants on the differentiation between national and EU authorisation was to find a robust way of deciding which authorisations should be decided on EU level and which could be decided on a national level. In this regard, criteria mentioned were related to overall costs and benefits but also how far other Member States are affected.

Only a few participants found the proposal of national authorisations worth exploring further. It was noted that SMEs could potentially benefit from national authorisations as those could result in lower costs, better understanding due to the national language and thus faster procedures. It was also pointed out that national authorisations could take account of local and national circumstances (e.g. only one production site) that EU authorisations cannot. Moreover, national and EU authorisations could be complementary and the increase in administrative burden could be prevented by mutual recognition rules. Other examples also combine the advantages of national and EU regulations. For example, the OSH and the
Industrial Emissions Directive work on the basis of national permits based on local risk assessments. Indeed, one participant argued that due to different national enforcement practices, it is less likely that national authorisations would lead to reduced harmonisation as the practices already differ.

11.3.9.2. International level playing field

Keeping an international level playing field was an important concern of many participants, who voiced concerns regarding the competitive situation of EU companies compared to their international competitors. In this regard, many participants argued that more efforts are needed to streamline hazard classifications, and other regulatory approaches internationally, to avoid disadvantages for EU companies. Also, other participants asked for the consideration of a similar approach as the Carbon Border Adjustment Mechanism proposed in the climate policy. Some participants argued that the EU should be a frontrunner in chemicals regulation helping other countries to advance protection. Some noted that even considering all the difficulties there is a possibility to regulate the process (e.g. EU legislations and international collaborations on illegal logging).

Furthermore, an important topic was the regulation of substances that are only used as process chemicals and are not part of the final product. It was suggested that the possibility be explored to reduce requirements for EU companies when the substance is used only in the process and a company is complying with the requirements of OSH and the Industrial Emissions Directive. All participants agreed that better regulation of imports is needed. However, as it is difficult to enforce any bans in imported goods, some participants suggested that such substances should be exempt from the authorisation process.

Equally importantly, some participants pointed out that the current efforts of the German national authorities (Monomer versus polymer) and the Chinese cosmetics regulation provide good examples of other methods for enforcing such regulations on imports.

11.3.9.3. Export bans

The discussion around export bans for products banned for use in the EU was very controversial, with many arguments shared among participants and no clear agreement reached. In particular, NGOs considered that not banning substances for export that are banned for use in the EU represents a double standard, as it would lead to lower protective standards abroad than in the EU. They also added that the EU should be a frontrunner in chemical regulation and that pesticides sector represents a good starting point for such a ban.

However, many industry representatives voiced reservations about export bans. They thought that both the risk situation and the needs of countries outside the EU can be different from the EU and argued that it would not be efficient for the EU to take the decision. Moreover, a particular substance of concern might be needed in other countries for medical devices for instance. Furthermore, participants added that multinational companies would produce the substances in different regions of the globe, and the effect on protection would therefore be small or even non-existent. It was clearly pointed out that the EU cannot regulate or prevent the use of the substance in third countries. Imposing the EU chemical regulation on third countries is therefore the wrong approach. Participants also discussed the difficulty of determining which substances should be banned for export if the substance is not completely banned and can be used in the EU for specific uses.

Participants proposed to use international fora to explore this further and to extend the scope of existing conventions. It was suggested to explore the approach used in the Basel convention (export of waste) and to set environmental standards of export and import of SVHC.
11.3.10. Interface REACH-other EU legislation

For this World Café Table, participants were asked the following questions: Would a stronger integration of regulating workplace-related risks create value added compared to the current situation? What aspects are to be considered? Should a stronger integration imply transfers of legislative tasks (i.e. certain BOELVs from OSH to REACH, or all worker protection measures from REACH to OSH)? Which route should be preferred? What are the elements that an impact assessment of such options consider? Are there additional options? Should there be a stronger integration of measures with permits under the Industrial Emissions Directive? Are there interfaces with other EU legislation which should be assessed as a priority?

11.3.10.1. Common views

The most discussed interface during the workshop was that between the REACH Regulation and OSH Directive. Most participants considered that the OSH Directive and REACH Regulation should remain separate. They added that OSH should be the main legislation to cover workers’ protection (occupational exposure limit to be kept under OSH), while REACH should complement this protection – e.g. for consumer uses. Benefits of OSH were mentioned compared to REACH, such as the representation of social partners, the hierarchy of risk management measures (substitution first), easier rules for companies to implement on site, and the fact that process-generated substances are covered under OSH.

Despite an overall synergy between OSH and REACH, the workshop participants noted that the interface still needs to be improved. For example, the scope of both legislations and their interaction should be better defined. Stakeholders noted that the debate, which started with the CARACAL paper, should be continued and all relevant Commission services (GROW, ENV and EMPL) should be involved.

All stakeholders present in the workshop agreed on the need to ensure links and synergies between the REACH Regulation and other pieces of EU legislation. The key pieces of legislation identified under this subject were: the Industrial Emissions Directive (IED), the Batteries Directive, the Waste Framework Directive, the Water Framework Directive, Legislation on Plant Protection Products, Biocidal Products Regulation, the Toy Safety Directive, the Regulation on Cosmetic Products and food contact materials legislation.

It was agreed that it is important to learn from other pieces of legislation in order to be more efficient and protective. Examples cited included the Restriction of Hazardous Substances and the End of Life Vehicles Directives. Additionally, all participants emphasised that when there are overlaps between EU legislations, it should be made clear to companies which legislation takes precedence.

11.3.10.2. Diverging views

Stakeholders had diverging views on the role of RMOA in improving the interface between REACH and other legislation. Industry representatives thought that RMOA should be made compulsory and that this should be the starting point to decide on the best legislation to address the risk from a specific use. Other participants suggested that increasing transparency by establishing some guidelines and criteria, along with involving OSH legislators/practitioners in RMOA, could ensure that the best risk management option is considered at the beginning of the regulatory process. However, NGOs disagreed and thought that compulsory RMOA would be an additional burden, slowing down regulatory action.
11.3.10.3. Additional points discussed

Additional points were raised during the discussions, such as the fact that IED could be used as an alternative to REACH to regulate environmental emissions, for example for PFAS. IED could also help improve the level playing field of EU companies compared to non-EU companies for process substances.

Safety Data Sheet (SDS) were reported to be sometimes difficult to understand for downstream users and that a simplification of supply chain communication would thus be welcomed, as well as a digitalisation of SDS. The SDS, however, should not become a burden for SMEs.

Stakeholders also mentioned that the risk assessment under the Biocidal Product Regulation evaluates non-active substances in biocidal products in a different way than REACH, and that for consistency purposes, it could be preferable that the Biocidal Product Regulation just refers to REACH for biocidal product components.

Some participants also advocated for more coherence across the EU legislation in the definition of “viable alternative”. Finally, some emphasised that the inclusion of Derived No Effect Levels and/or Predicted No Effect Concentrations (PNECs) in harmonised classification and labelling under the Classification, Labelling and Packaging Regulation would create more issues (e.g. timely update of harmonised classification and labelling when new data is available).

11.3.11. Innovation and how to support substitution; improving enforceability and impact on SMEs

For this World Café Table, participants were asked the following questions: What is your view on the use of financial instruments to incentivise substitution at EU level? How could such financial instruments be designed? Are there any other ideas on how to promote innovation and substitution under REACH? What is your view on giving the Forum a similar role as RAC and SEAC? What measures can be taken to accommodate specific constraints of SMEs?

11.3.12. Common views

Most participants agreed that innovation is particularly important for the substitution of hazardous substances. There was also agreement that already in the current system there is an incentive to substitute.

Additionally, many participants emphasised that substitution is a complex process and is particularly challenging for SMEs. For example, SMEs are often bound by what their customers demand from them and therefore there is limited margin for them to substitute.

All agreed on the key role of enforcement as a means to ensure a correct implementation of regulation and for a level playing field between EU Member States. But it was pointed out that the resources allocated to enforcement vary greatly across Member States. In this view, some stakeholders mentioned that changing the role of the Forum could contribute to improved enforcement. Several participants stressed the importance of having appropriate analytical methods for chemical analysis.

Finally, many stakeholders emphasised that SMEs face significant challenges in complying with REACH. Preparing authorisation applications often requires more resources and knowledge than available for SMEs. Therefore, improved support to SMEs would be
Important for helping SMEs to substitute their use of hazardous substances. It was remarked that the commitment to alleviate the burden on SMEs should be made compatible with increasing the level of protection of human health and the environment.

11.3.13. Diverging views

It was noted that innovation is not good per se. Some indicated that regulation should indicate the way to follow.

Introducing a financial instrument for increasing the incentive to innovate and substitute was a contested proposal. Industry representatives argued that there are already sufficient incentives for substitution. It was also stated that industry already pays for the preparation and submitting of an application for authorisation for example. Adding more fees could divert resources from innovation and substitution. This is especially true for SMEs. Other arguments against a financial instrument focused on the challenge of designing a fair system – e.g. when the use is essential and there are no alternatives. Securing a level playing field between EU and non-EU companies was also mentioned as a practical challenge. Industry defended the need to focus on substituting the risk, not the hazard.

However, NGOs supported the idea of a financial instrument. It was mentioned that it would increase the incentive for substitution and that it could provide funding for research on alternatives and substitution. It was mentioned that the model employed by the US state of Massachusetts was working well in promoting substitution, although it was also acknowledged that this might be a result of the different regulatory systems in the US. It was also mentioned that implementing a model similar to this one would allow useful information to be gathered on the volumes used of the substances and on which substances are present in or used for which articles or products.

Some participants suggested making the substitution plans mandatory in all applications for authorisation and pointed to the need to ensure their implementation during the authorisation period. It was also suggested to limit the number of authorisations that can be granted subsequently and to avoid the time-unlimited derogations from restrictions. These were considered to be useful means to incentivise substitution.

While there was an overall agreement on the importance of improving enforcement, there were diverging views on the role of the Forum. Strengthening the role of the Forum to provide more weight to the enforceability of restrictions and authorisations received support. The Forum was considered to represent the voice of implementation in the decision process, and it is therefore important to strengthen its role. Some favour affording the Forum the same weight as the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC).

Nevertheless, several participants raised concerns about the idea to give the Forum a more formal role. They were concerned that the Forum would then create more complexity overall in the processes. A strengthened role would require full transparency and the engagement of all Member States.

11.3.14. Additional points discussed

It was suggested that existing financial tools should be used more. Horizon Europe was mentioned as an example of a funding mechanism, which can support innovation. It was suggested that this tool could provide more support to SMEs in their efforts to substitute regulated substances. Other existing financial tools, for example, tax reductions could provide additional incentives for innovation and substitution.
Participants supporting the introduction of a financial instrument similar to the American system of the Toxics Use Reduction Act (TURA) added suggestions on what could be the scope of fees for those using certain hazardous substances. They suggested that the fee should be placed on use from the placing of a substance on the candidate list. It was also suggested to apply the fee for the use of restricted substances where there was a derogation or a transition period. Then, the fee should increase over time to strengthen the incentive.

Related to the discussion on substitution, it was suggested to initiate studies and market analysis of the availability of alternatives, both substances and technologies, at an early stage of the authorisation process.

On the issue of enforceability, discussions highlighted other issues considered to be important, such as inadequate resource allocation in some Member States.

11.4. Conclusions of discussions

11.4.1. Common views

Many common views emerged from the discussions on key elements of the REACH Regulation revision. It was unanimously agreed that there is a need to revise the authorisation and restriction processes of REACH. Even though the problem analysis was overall well defined by the European Commission, stakeholders considered that the policy options for the reform could be further detailed, notably to explain how each option would solve each of the identified problems.

Across the world café tables, stakeholders overall agreed on what are the main problems of the REACH Regulation authorisation and restriction system, on top of the ones already identified by the Commission in the background document. Among others, the issue of inefficiency and delays of the authorisation/restriction process was raised, linked to burdensome procedures. Stakeholders also highlighted the importance of legal certainty concerning the outcome of applications for authorisation, but also in terms of review period. Also, the challenges around imported articles were emphasised, due to the impact they can have on the level playing field between EU and non-EU companies.

The discussions revealed a lack of clear consensus among stakeholders on a preferred policy option, notably due to the level of information provided so far on these options being too high. However, it appeared that Option 1 could be the easiest and most reliable solution. The industry also considered Option 2 to be favourable, although its outcome was assessed to be uncertain and lacking a clear scope. It was also thought that it could render the authorisation/exemption process more complex than the current one. Finally, there was a broad consensus that Option 3 is not viable and too radical.

Participants were mostly against the introduction of national authorisations, arguing that it would result in reduced harmonisation efforts, increased administrative burden for national authorities and additional political pressure at national level. Participants were also in favour of an international level playing field, while acknowledging possible difficulties stemming from its implementation.

Concerning the interface between REACH and other EU legislation, most stakeholders agreed that synergies between OSH and REACH should be improved. For example, the scope of both legislation and their interaction should be better defined. The interface between REACH and other pieces of EU legislation (such as Industrial Emissions Directive, Batteries Directive, Waste Framework Directive) could also be improved.

The majority of participants agreed that innovation is very important for substitution of hazardous substances. They also agreed that the current system already includes an
incentive to substitute. Many of the participants emphasised that substitution is a complex process and that it is particularly challenging for SMEs.

11.4.2. Diverging views

Despite an overall consensus on many issues linked to the REACH Regulation authorisation and restriction process, stakeholders also had diverging views on few elements, such as the overall objective of the new REACH Regulation. Some stakeholders suggested that the focus should be on substitution of substances, while others argued that emphasis should be placed on risk management.

Another point of divergence concerned the authorisation process, which is considered by industry to be too burdensome and stifling innovation, while NGOs disagreed. They emphasised that applying for authorisation should entail a level of burden in order to incentivise the substitution of SVHCs.

Industry and NGOs also differed on who should bear the burden of proof during the applications for authorisation or for derogations under the new policy options being discussed. Opinions further diverged on the route to follow for granting the authorisations. NGOs highlighted that it would be relevant to implement only one route, the adequate control route, where risk would need to be proven to be minimised and without socio-economic assessment. However, industry argued that the socio-economic assessment brings proportionality to the debate and should be an assessment that considers all the possible dimensions.

Opposing views were also noted on the RMOA, with industry stakeholders considering that they should be made compulsory and be the starting point for deciding the best regulatory approach to address the risk. Other stakeholders, however, thought that compulsory RMOA would be an additional burden, slowing down the regulatory process.

11.4.3. Additional points

Many additional points were raised during the workshop discussions concerning, for example, the range of industrial sectors considered in REACH reform as well as the complexity of the value chains. It was suggested that a more sectoral approach could be adopted when revising the REACH authorisation and restriction process. Additionally, regrettable substitution could be included as an important challenge when tailoring objectives of the reform, as some of the industry representatives were worried that the alternatives they are developing would also be restricted.

Furthermore, when clarifying the authorisation system (Option 1), attention should be paid to the essential use concept, the definition of loss of performance and substitution plan. Improved coordination among actors taking part in the authorisation and restriction system would also be important.

Finally, stakeholders asked for the candidate list to play a greater role. It was argued that the list could be an essential part of the promotion of innovation. This could encourage companies to provide a comprehensive analysis on the substitutions. Several stakeholders added that the candidate list could trigger the provision of information from the users.

List of abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>CARACAL</td>
<td>Competent Authorities for REACH and CLP</td>
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<tr>
<td>CAS</td>
<td>Chemical Abstract Service</td>
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<tr>
<td>CLP</td>
<td>Classification, Labelling and Packaging Regulation (EC) No 1272/2008</td>
</tr>
<tr>
<td>DUs</td>
<td>Downstream users</td>
</tr>
<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td>ED</td>
<td>Endocrine disruptors</td>
</tr>
<tr>
<td>REACH</td>
<td>Registration, Evaluation, Authorisation and Restriction of Chemicals</td>
</tr>
<tr>
<td>RoHS</td>
<td>Restriction of Hazardous Substances in Electrical and Electronic Equipment</td>
</tr>
<tr>
<td>SCIP</td>
<td>Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive</td>
</tr>
<tr>
<td>SR&amp;D</td>
<td>Scientific Research &amp; Development</td>
</tr>
<tr>
<td>SVHCs</td>
<td>Substances of Very High Concern</td>
</tr>
<tr>
<td>TF</td>
<td>Technical function</td>
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12.1. Executive summary

On the 21st of March 2022, an online workshop on the extension of the generic approach to risk management (GRA) under the REACH Regulation. The workshop was organised in the context of the planned reform of the REACH authorisation and restriction system based on the 2018 REACH Review and as announced in the Chemicals Strategy for Sustainability. The planned reform aims to build on the positive experiences in implementing the REACH authorisation and restriction processes and address their current weaknesses and inefficiencies.

The main objective of the workshop was to present the first results and assumptions made on uses of the most harmful substances in the course of the work. Participants were invited to critically review the information extracted from the registration data and the use maps prepared based on that data, validate and complete where necessary. At the later stage, developed use maps will serve as a basis to assess the impacts of potential restrictions based on generic risk assumptions.

The workshop was organised in two plenary-informative sessions, and eight interactive break-out groups allowing participants to provide feedback to the questions concerning the options and elements addressed in the impact assessment. Participants were assigned to one of eight groups:

- **Group 1 - PC 32**: Polymer preparations and compounds, PC 19: Intermediate
- **Group 2 - PC 1**: Adhesives, sealants, PC 9c: Finger paint, PC 9b: Fillers, putties, plasters, modelling clay, PC 9a: Coatings and paints, thinners, paint removers
- **Group 3 - PC 21**: Laboratory chemicals (not exempted from REACH)
- **Group 4 - PC 34**: Textile dyes, and impregnating products, PC 23: Leather treatment products, PC 18: Ink and toners
- **Group 6 - PC 35**: Washing and cleaning products; PC 4: Anti-freeze and de-icing products, PC 8 biocidal products
- **Group 7 - PC 39**: Cosmetics, personal care products, PC 28: Perfumes, fragrances, PC 3: Air care products, PC 29: Pharmaceuticals
- **Group 8**: Complex articles

Participants of the break out groups have not identified any major gaps in the use maps presented. However, some overestimation of uses were pointed out due to the fact that often registrants have included a higher number of uses in their registration dossiers to be on the safe side, but that some of these uses might not take place in reality. It was suggested that an assessment of the frequency a substance has been assigned to certain uses could help narrowing down the use map.

In terms of methodological challenges, most participants found it difficult to contribute to the discussion without a specific list to substances, which was not communicated due to confidentiality issues with some registration data. Therefore, it was difficult for industry...
representatives to assess the impact of introduction of GRA on their companies. In addition, when analysing registration dossiers the attention should be paid to possible obsolete and inaccurate data given the changes over time.

There was a wide agreement that there is a need for more clarity on the definition of professional use both in terms of differentiating it from industrial use and from consumer use.

Summaries from these break-out groups are presented in this report.

12.2. Introduction

12.2.1. General context and objective of the workshop

On 21 March 2022, the European Commission held an online workshop on the extension of the generic approach to risk management (GRA) under the REACH Regulation. The main objective of the workshop was to present the first results and assumptions made in the course of the work and discuss those with stakeholders. Participants were invited to question and validate the approach taken on the use maps to complement and correct the data gathered so far. At the latter stage, these developed use maps will serve as a basis to assess the impacts of potential restrictions based on generic risk assumptions. The results of the impact assessment will be presented in the fourth and last workshop on the 7th of June 2022.

This workshop was part of a series of four events planned as part of the ongoing project “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction”. The first two workshops took place on the 9th and 12th of November 2021, targeting respectively Member State competent authorities as well as stakeholders from the industry and civil society. Both addressed the reform of the REACH Authorisation and Restriction processes.

The workshops are part of the wider consultations planned for the impact assessment of the revision of the REACH Regulation, including a Public Consultation (from January to April 2022), as well as targeted consultations in the form of questionnaires, and follow-up interviews. Several contractors are supporting the Commission in the impact assessment work. For the revision of authorisation and restriction under REACH, a specific study is being carried out by a consortium of consultancies (VVA Consortium).

12.2.2. Workshop organisation

The workshop was held online on the Microsoft Teams platform. The agenda of the workshop is available in Annex 1 of this report.

The stakeholders were provided before the workshop with a workshop background paper (Annex 2), presenting all the necessary information on the subject to inform the discussions at the workshop. After the opening session, two rounds of the break-out groups were organised, each running for around an hour and half. The first round took place in the morning and the second round in the afternoon.

The Commission invited stakeholders to provide feedback on the use maps across eight dedicated break-out groups. Participants were asked to register to the group of their preference within the limit of places available. The product categories discussed in each of the eight break-out groups is presented in detail in the text box below.
Topics discussed in the break-out groups (morning and afternoon):

- Group 1 - PC 32: Polymer preparations and compounds, PC 19: Intermediate
- Group 2 - PC 1: Adhesives, sealants, PC 9c: Finger paint, PC 9b: Fillers, putties, plasters, modelling clay, PC 9a: Coatings and paints, thinners, paint removes
- Group 3 - PC 21: Laboratory chemicals (not exempted from REACH)
- Group 4 - PC 34: Textile dyes, and impregnating products, PC 23: Leather treatment products, PC 18: Ink and toners
- Group 6 - PC 35: Washing and cleaning products; PC 4: Anti-freeze and de-icing products; PC 8 biocidal products
- Group 7 - PC 39: Cosmetics, personal care products, PC 28: Perfumes, fragrances, PC 3: Air care products, PC 29: Pharmaceuticals
- Group 8: Complex articles

A moderator and a rapporteur were allocated to each of the eight groups. A summary of discussions was reported back to the plenary session. While the opening and closing sessions of the workshop were accessible to any registered participant, the break-out groups were accessible only to the participants who registered as active.

Finally, the participants were invited to submit their written contributions to the European Commission by email (GROW-ENV-REACH-REVISION@ec.europa.eu) by the 8th April 2022.

12.2.3. Participants

The online opening and closing session were open to all registered participants. Active participation in the break-out groups was limited to those who had registered as ‘active’ participants. The plenary sessions were attended by around 400 participants, while the break-out groups gathered around 20 participants each (in total, 184 stakeholders registered for the break-out sessions).

Various types of stakeholders took part as active participants in the break-out groups, including companies and industry associations, NGOs and public authorities. The number of participants per type is presented in Figure 1 below.
Different industry sectors were represented: chemicals and polymers, healthcare, industrial processes and general industry, paint and printing inks, minerals and metals, cleaning products, petrochemical industry, energy processes, automotive industry, aerospace, textiles and fibres, cosmetic products or construction industry. Figure 2 below shows the number of participants per type of industry sector they represented.

"Other" refers to industry sectors that were not represented in the industry groups listed in the graph, and for which only one representative was present in the discussions, such as: cookware, nanotechnology, tobacco, telecom, furniture.
12.2.4. Summary of the introductory session

As an introductory note, Ms Kristin Schreiber (Director at DG GROW, European Commission) provided a welcome speech introducing the context of the REACH reform and the workshop’s objectives. Ms Schreiber explained that the extension of GRA announced in the Chemicals Strategy for Sustainability (CSS) aimed at speeding up the substitution of the most harmful chemicals through amendments of the REACH Regulation and other chemicals legislation.

She recalled three main reasons why substitution is not fast enough:
- Complex authorisation or restrictions processes – this was the subject of two workshops in November 2021
- Inappropriate criteria and tools to assess authorisations and restrictions – this was the subject of a workshop on the essential use workshop on 3 March
- Detail of required analysis:

Currently, competent authorities need to demonstrate an unacceptable risk for substances before they can be restricted, which provides strong scientific evidence for the restrictions. However, this approach presents an important challenge for authorities in terms of availability of data to demonstrate those risks. In particular, data on uses, which was the subject of the workshop, is hardly accessible to the authorities and often incomplete. Moreover, the restriction process of individual substances is lengthy and bears the risk of regrettable substitution.

This issue should be addressed through the extension of the generic approach to risk management, which has already been successfully implemented for carcinogenic, mutagenic and reprotoxic (CMR) substances for consumer uses, to further hazard classes and to professional uses. This will be the subject of the 21 March workshop and part of a study which assesses different options to address the above-mentioned issues.

Subsequently, Ms Kristin Schreiber (Director at DG GROW, European Commission) presented the background of the workshop and the GRA concept.

The GRA concept will be implemented in REACH through an empowerment of the Commission to introduce restrictions through implementing regulations. This means that the Commission is allowed, but not obliged to propose such restrictions for all substances and uses within the empowerment. Implementation will take place in a stepwise manner.

As the empowerment alone does not have any direct impacts, and as assessing the impact of the entire scope of potential restrictions would give excessively high figures, including for restrictions that might not happen at all or only in the very distant future, it is necessary to define more realistic scenarios, in order to give a correct assessment of likely impacts. However, as decisions on the exact scope and timing of restrictions would happen only at a later stage, it is necessary to work with assumptions on the scope and timing of such restrictions.

Ms Schreiber underlined the challenges of identifying the concerned substances, especially for hazard classes where currently there are no classification criteria. Moreover, REACH registration data identify the uses only in general terms, and thus further information sources will be needed. As this is an enormous task, it will be necessary to focus on the most important substances and uses, in particular those which are likely to prioritised first for upcoming restrictions, and to work with substantiated estimates for the remaining substances and uses. Further information sources will be needed, and data need to be

\[\text{A situation in which a substance can be replaced by a substance that might not be significantly less hazardous.}\]
cross-checked with stakeholders, which is the purpose of the workshop and the contributions sought from workshop participants.

Following the opening speeches by the Commission, consultants from Ricardo presented the results of their Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability\textsuperscript{1} commissioned by the European Chemicals Industry Council (CEFIC). This study sought to assess the economic impacts on the EU chemicals industry resulting from the inclusion of additional hazard classes in the CLP Regulation and the extension of GRA to additional hazard classes and professional uses, as announced in the CSS. The methodology was presented along with the list of substances to be regulated and selected scenarios. Two timelines were used for the analysis of impacts. Moreover, the shares of companies portfolio expected to be impacted by the introduction of GRA, and the affected sales volumes on given sectors were presented. The presentation by Ricardo is provided as Annex 3.

The plenary morning session was closed with a presentation for the VVA Consortium. The methodology and the preliminary results of the use mapping were presented. It was highlighted that the GRA could cover substances on their own, their mixtures and in articles. It would also cover the import of articles if it is specified in the scope of the proposed restriction. Based on identified uses, the study will assess the potential impacts of the extended GRA, which will include considerations of different options of how the GRA could be implemented. The study is also looking at how the future restriction and authorisation processes could be designed. The starting point of the research is a master list of substances with intrinsic properties that might be considered under GRA. These substances are grouped by hazard class and divided into two baskets: Basket 1 contains substances for which the hazards are confirmed while Basket 2 contains substances for which the hazard is likely. The list contains about 700 substances. The list of substances and respective hazardous properties were retrieved by ECHA from the REACH registration dossiers. For other hazard classes, data from SVHCs, PBTs, or EDs were considered.

Regarding uses, the importance to define well consumer and professional uses was highlighted for the implementation of GRA. When taking the data from the registration dossiers, the study team gathered the uses as assigned by the registrants. The study team indicated that the GRA is likely to be applied to uses by professionals when these are similar to uses by consumers, regarding the assumed risks.

Finally, it was noted that the objective of the different break-out groups was to scrutinise the findings based on the registration dossiers and presented in the use maps. It was highlighted that data from registration dossiers present some limitations, for example, in terms of lack of updates. The stakeholders were invited to fill the existing data gaps, to the extent possible, in the break-out group discussions. The presentation by the VVA Consortium is provided as (Annex 4).

At the end of the opening plenary session, stakeholders were invited to ask questions and comment on the presentations given. Stakeholders inquired about the data on substances used in both the CEFIC and the VVA Consortium studies. The scope of CEFIC study covers around 12,000 substances and 3 groupings from ECHA, however it included a broader number of substances than the ECHA list of substances. It was clarified that the use mapping presented during the workshop is based on the harmonised classifications and for the classification from registration dossiers for Basket 1. Equally, in case of Basket 2, the registration dossiers set out a basis. A third Basket 3 of substances has not been included in the analysis as the data was not deemed to be sufficiently complete. Concerning CMR substances, only hazard categories 1A and 1B were considered, as based on harmonized classification and Annex 6 of the CLP Regulation. The endocrine disruptors list was developed based on recommendations provided by ECHA. The Consortium highlighted that

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there is some degree of uncertainty for hazard classes for which the criteria are still under discussion, such as PMT substances.

Stakeholders also inquired about various issues, such as an export ban on substances, the interconnection between GRA and the essential use concept, the importance of downstream users as well as the GRA application. The discussion further revolved on uses and the specific challenges of restricting mixtures or articles.

The European Commission highlighted that the data from downstream users would play an important part for the assessment of expected impacts of the regulatory change. Some factors, such as new alternative products, the transfer of jobs outside of the EU will be considered. The European Commission highlighted that mixtures would be prioritised within the work plan of restrictions as it is the area where most of the exposure is to be expected. Restrictions on articles are more complex but will also be under scrutiny. Due to the vast array of substances and uses, it was necessary to prioritise the assessment to the most relevant substances and uses, in particular those that are most likely to be restricted first, and to use substantiated estimates for those that might eventually be restricted at a later stage. The European Commission explained that professional uses are limited to uses taking place outside industrial settings. It was clear that there are borderline cases to industrial uses which might need to be clarified. The Commission also explained that one option was also to focus restrictions on only certain professional uses where the exposure risk was high and measures to control exposure control were difficult to implement. The European Commission added that the existing reviews and evaluations of REACH had been taken into account in the studies.

Finally, it was highlighted by a few stakeholders that the impacts of introducing restrictions is not necessarily linked to the number of substances restricted, as each restriction and substance could have a wide range of impacts depending on the substance's importance and its substitutability. The European Commission explained that the aim of the study was to understand which substances and uses are the main drivers for the overall impact. Derogations could reduce these impacts but it was difficult to assess at this stage whether to what degree such derogations would be necessary and eventually granted.

12.3. Break-out groups

The aim of the workshop and the break-out groups was to critically review the information extracted from the registration dossiers and the use maps prepared based on that data, and validate them with participants. Feedback and input on the following aspects was particularly important for the discussions:

- Assumptions on the number of substances in the individual hazard classes,
- The identified products (mixtures and articles),
- Detailed information on products (especially articles) down the supply chain that depend on the availability of the substances,
- The level of technical functionalities.

The groups also aimed at assessing how the use maps could be further improved. This section introduces the key points that emerged from the discussions in each of the eight break-out groups. To help participants prepare for the discussion, a workshop paper and the presentations on the preliminary results of the use mapping was shared in advance with the participants. In addition, the preliminary results of the use mapping were presented at the start of the each break out session.
The summary of the break out groups provided below can sometimes differ one from another, as the discussion often took different paths aligned with the needs of active participants.

12.3.1. Group 1 - PC 32: Polymer preparations and compounds, PC 19: Intermediate

The break-out group was composed of companies and sector associations mostly from the plastics and chemical industries. These covered actors from polymer producers (thermoplastics, reactive prepolymer mixtures, additives). Furthermore, a downstream sector association of plastic converters was present, as well as some representatives from Member States Competent Authorities.

**Missing uses, technical functions or products**

In general, participants were not able to give direct information on missing uses. Overall, the impression of individual sector representatives was that technical functions typical for their product area were relatively well represented. It was seen as rather problematic that PC 32 is so broad that no false positive or false negative areas can be easily identified. It was suggested that the project team should have follow-up discussions with sector representatives of the group (and possibly other stakeholders). For this purpose, participants suggested using a matrix in which application areas such as polymer types or basic chemistry types, e.g., phenolic resins, epoxy resins, etc., are plotted against frequently occurring TFS to determine relevance for market segments. Given the timeline of the project and the ambition of the European Commission, such a matrix may need to be kept quite generic to avoid the need for technical experts to do in-depth analysis before answering and to be able to facilitate responses.

Regarding the main affected sectors, participants also referred to official sector statistics as a valuable source to narrow down the list of end uses (and products related to them).

**Methodological challenges of the use map identified**

Regarding the relation between PC 32 ‘Polymers’ and PC 19 ‘Intermediates’, participants agreed with the assessment of the project team for PC 32 uses could be more precisely identified than for PC 19. This points to a regularly incorrect use of the intermediate definition in the registration dossiers. Some participants indicated that this could change if the definition of intermediates is modified in the future, as currently discussed. However, the project is based on the current definition used in registration dossiers and it will not be possible to reflect possible upcoming changes in the definition.

In response to a question from the participants, it was clarified that polymers as such are not included in the substance lists or appear in the use maps, which are based on registration data. Participants pointed out that it would be important to check against what extent the monomers, which often have several hazardous properties are used under industrial conditions, are included in the lists through which polymers are registered according to Article 6(3).

Often, registrations of monomers contain the end uses of the subsequent polymers, which can lead to an overestimation of the number of hazardous substances in a PC. In addition, it may be that in such cases, also for other reactive components in polymer mixtures, articles are indicated in which the substance as such is no longer contained, e.g., as it has become part of a larger polymer complex from which it can no longer be released. In a similar way, rubber products were discussed as the vulcanization process also leads to incorporation of ongoing substances and the end of their existence as such – it remained open if there are areas where substances remain in the products.
A question was raised on whether a preliminary risk assessment, e.g. in terms of people exposed, frequency of use etc., would be helpful to identify areas where risk might exist for consumers or professional users. It was clarified that the understanding of the project team is that the question of risk is exactly not what should be addressed but only the presence of substances with certain hazardous properties, so that the full overview of potential restriction scenarios can be considered. Furthermore, the scope of the “risk area” is defined by the political setting in the CSS and thus the substances need to be covered as well as the uses. However, it is expected to differ in the impacts allocated to the use areas.

Participants enquired on the reason why vPrM substances were not included in the assessment, contrary to vPvB substances. It was clarified that this was mainly due to the unclear criteria for this hazard and the high level of uncertainty associated.

A key challenge for participants to contribute to the discussion was the lack of specific lists of substances that would be affected. It was clarified that this is due to confidentiality issues with some registration data.

As an overarching remark, participants suggested that an assessment of the frequency a substances has been assigned to certain uses could help narrowing down the use map. It was clarified that in the initial use map all assignments were included regardless of the frequency. It was acknowledged that this parameter could be relevant for the impact assessment, as the frequency of selection of a product or a technical function might be a proxy for the main uses and niche applications. In particular, products used with a very low frequency might have lower impacts as they might no longer be on the market, or be linked to smaller supply chains etc. Nonetheless, they should still be included in the use map to have a good overview of all uses as far as possible.

It was discussed whether the sector of use or article category would not serve as a better indicator for use maps than PC. However, it was concluded that this is not the case as this information is often missing.

**Data challenges of registration data to be considered in the use map**

Companies indicated that they are already screening their portfolios to assess the degree to which they might be affected by an extension of GRA. However, this is proving difficult for hazards such as ED and PMT, where criteria are still under discussion and not yet defined.

Participants also highlighted that use descriptors in the ECHA guidance document (R12) were not designed for the task performed in the project. These use descriptors were rather designed to allow an efficient risk assessment in registration and to communicate back to the supply chain to enable downstream users in identifying themselves in the exposure scenarios communicated. Therefore, participants were a bit critical on how the registration data are currently used for the use maps and raised concerns on the level of uncertainty and unspecificity. Therefore, participants advised that the registration data is carefully interpreted for finalising the use maps.

**Other aspects in regard to further development of the Impact assessment**

Participants identified one important challenge for the assessment of impacts, namely to the difficulty in distinguishing between professional and industrial uses, since there are many uses that are borderline.

It was furthermore emphasized that human health and environmental benefits should be assessed carefully and quantified to the extent possible. More generally, costs and benefits of the process should be assessed to demonstrate what is the added value of GRA compared to other regulatory approaches.
Participants also highlighted that the impacts of extending the scope of GRA should be seen in the context of other elements currently discussed in the REACH revision. It was indicated that changes that might be considered as benefits in an isolated view can be more complex and burdensome if assessed in combination with other changes. Hence, this deserves careful consideration in the overall REACH impact assessment.

Finally, some participants suggested developing some pilot cases to get to the level of granularity needed in the impact assessment.

Additional relevant data sources and stakeholders

- **Data sources**

- **Stakeholders**
  - Cefic
  - ETRMA
  - European Phenolic Resins Association (EPRA)
  - European Federation for Construction Chemicals (EFCC)
  - European MasterBatchers and Compounders
  - European Plastics Converters
  - PlasticsEurope
  - Individual companies (e.g. BASF, Solvay etc.)
  - Karlsruhe Institute of Technology (KIT)
  - Member States Competent Authorities

12.3.2. Group 2 - PC 1: Adhesives, sealants, PC 9c: Finger paint, PC 9b: Fillers, putties, plasters, modelling clay, PC 9a: Coatings and paints, thinners, paint removes

The break-out group was composed of companies and sector associations mostly representing adhesive and sealant, construction, and colouring industries. These covered various actors, including some representatives from the ceramic and glass industry. Some representatives from Member States Competent Authorities were also present.

**Methodological challenges of the use map identified**

The participants found the use maps difficult to interpret and validate without knowing the relevant substances. They remarked that use maps are just a snapshot in time and may not
reflect the evolution in the uses and quantities per use of the substances (where this information is provided).

The participants discussed whether the impact assessment could follow a worst-case scenario approach or whether it is possible to select a representative sample of substances per product category. With regard to the latter, participants highlighted that it is a very difficult exercise and could be a nearly impossible task without access to the master list of substances potentially classified, which in any case could result in anecdotal evidence. Also the selection of a representative sample of mixtures and articles (to be coupled with information on the concentration levels of substances) is a very difficult task: mixtures and articles are very complex ‘systems’ and information on concentration is not publicly or easily available for most of them.

The impact assessment should also carefully consider impacts on innovation such as the loss of valuable chemistry and its potential substitution with less studied chemistry, which constitutes regrettable substitution.

**Data challenges of registration data to be considered in the use map**

The participants stressed that in many cases, registration dossier submitters selected many or all use descriptors (in particular chemical product categories) to be on the ‘safe side’.

**Existing knowledge on articles potentially under the extended scope of the GRA**

All hazard classes under consideration may be relevant for substances used in these product categories.

Adhesives, sealants, coatings and paints are used in virtually all kinds of articles. Participants enquired whether the Commission was considering concentration thresholds (e.g., 0.1% or 0.01% of substance in a mixture/article). They underlined the importance of defining ‘professional use’ vs ‘industrial use’ vs ‘consumer use’.

**Additional relevant data sources and stakeholders**

The participants suggested to crosscheck the use maps available on ECHA website and prepared by the industry associations to validate to a certain extent the information from the use mapping exercise carried out by the consultants. They also suggested to make use of the information prepared by the industry for the cost assessment carried out by Ricardo for Cefic, although there is a need to ensure confidentiality.

For further discussion with industry, the consultants could explore some form of grouping (e.g., monomers, additives) of the substances potentially affected.

**Other aspects in regard to further development of the Impact assessment**

The participants considered that, in order to carry out a meaningful impact assessment, additional elements will have to be defined:

- Essential use;
- Assuming the implementation of the GRA, where and when uses and exposure would be considered;
- The impact assessment boundaries: are the consequences for downstream users going to be considered? How are the market value differences between substances, mixtures and articles going to be considered? Are the impacts on the technical
performance of products going to be considered? How? For example, coatings and paints are often used to enhance the durability of products and infrastructure. Alternatives to a particular substance may have a safer toxicological profile but a lower technical performance, requiring a higher frequency of application, which may result in a lower overall environmental performance.

The participants also provided a note of caution on using technical functions to make any consideration on the availability of alternatives, as availability and affordability of alternatives depends also on the number of uses of the substance, among other factors. Also, it is not possible to assume that substances with the same technical functions can be interchangeable in all kinds of mixtures.

12.3.3. Group 3 - PC 21: Laboratory chemicals (not exempted from REACH)

The break-out group was composed of companies and sector associations mostly representatives of the pharmaceutical and medical technology industries. Furthermore, some representatives of nanotechnology, tobacco and the veterinary industries were also present. Several representatives from Member States Competent Authorities were also present.

General issues discussed

The definition of what is a "laboratory chemical" as a substance or mixture used in a laboratory was stated to require further clarification to avoid misunderstandings. However, all participants agreed that an analysis of manufactured substances to control their quality (purity, composition etc.) would not be regarded as a laboratory chemical, i.e., the chemicals needed to analyse another chemical are laboratory chemicals, while the chemical being analysed is not.

Quality control should be covered under the "manufacturing process" in the chemical safety assessment but not lead to the assignment of PC 21.

The group discussed whether SR&D exemptions would actually be used by laboratories if their chemicals were restricted. In this regard, it was highlighted that it is unclear how to interpret the term "controlled conditions" in the SR&D definition (Art 3(23) REACH), creating uncertainties and potentially preventing the use of the exemption.

Several members of the group regarded the differentiation between professional uses and industrial uses as debatable. The exact same laboratory activities with exactly the same risk management measures for workers and environmental protection could be carried out in a hospital and in an industrial installation. The laboratory chemical applied in a hospital would then fall under a GRA (professional use), while the use in an installation would not (industrial use). Also regarding the highly trained staff in laboratories, this was pointed out as problematic with regard to the GRA implementation and/or the definition of professional and industrial uses in ECHA’s guidance documents.

Missing uses, technical functions or products

The stakeholders in the group stressed that it was difficult to state whether or not uses, technical functions and products listed in the slides are plausible, or if any are missing, without knowing the substances to which the PC 21 had been assigned. Overall, laboratory chemicals could have a large variety of technical functions and be applied in many different products.
Some members of the group agreed that some of the technical functions and relevant products presented on the slides were unlikely to be correctly assigned to substances registered for the PC21. This was particularly stated for some of the consumer applications (e.g. plating agent). The explanation of “research and development” for consumers was confirmed as possible, e.g. in the context of school education.

**Methodological challenges of the use map identified**

The core methodological challenge identified by the participants was the impossibility to assess if uses were relevant and current or if substances had been registered for PC21 to ensure a full market coverage and no update had taken place.

It was also stated that the granularity of information on the uses is not sufficient for the impact assessment, specifically with regard to the lack of information that allows deciding on the essentiality of a functionality, e.g. in the health sector.

An external validation of the registered uses and the pertaining technical functions/explanation of products would not be possible without knowledge of the substances.

**Data challenges of registration data to be considered in the use map**

It was confirmed that many chemicals were used in a laboratory context, including in very small amounts. Therefore, the high number of substances registered in PC21 was not surprising to the stakeholders.

In addition to that, the participants of the break-out group stressed that a large number of laboratory chemicals were not registered under REACH but could be subject to restrictions. Substances which are “amongst others” used for laboratory purposes may not always be registered for a laboratory use. In addition, many laboratories may use import chemicals below the tonnage threshold and impacts from GRA restrictions on these would not be part of the impact assessment as they are not included in the registration database. It was also regarded as possible that chemicals are only used for laboratory purposes and in very low amounts. These substances might be (unintentionally) affected by a GRA restriction that refers to hazardous properties rather than providing substance lists to define the scope.

It was stated that safety data sheets would (still) not contain any exposure scenarios and would not always indicate for which products/uses a chemical has been registered. Therefore, it cannot be expected that uses are notified to ECHA and thus become known and considered in the development of restriction proposals.

To mitigate the gaps and uncertainties about the presented information from registration dossiers, it was suggested to consult the registrants as the best improvement option. In addition, sector assessments could be used, such as the study by CEFIC on the potential impacts of the GRA. Participants also suggested to make use of existing data sources already in the hands of ECHA, such as the SCIP database, or the DU notifications.

**Existing knowledge on articles potentially under the extended scope of the GRA**

In general, and in accordance with the name of the product category, articles were considered as the exception in the PC21. However, the product specification “photographic paper” was considered as generally plausible. No clear opinion could be developed on this aspect.

It was clearly stated that laboratory equipment and/or medical devices should not be registered with the PC21.
Additional relevant data sources and stakeholders

- It was reported that laboratories in Sweden must register all hazardous chemicals they use. This data may be valuable to verify the registration data for the impact assessment.
- One stakeholder reported to have assessed the potential impacts of GRA on their portfolio and agreed to share the results with the consultants if confidentiality is ensured.

The lack of information on which substances would fall into which of the expected future CLP hazard classes would make it more difficult for downstream users to assess the impacts. However, the medical sector highlighted that they expect substantial impacts on their operations from the GRA as well as from the grouping of chemicals. Both would increase uncertainties and burden on industries.

12.3.4. Group 4 - PC 34: Textile dyes, and impregnating products, PC 23: Leather treatment products, PC 18: Ink and toners

The break-out group was composed of companies and sector associations mostly representatives of pigments and textiles industries. Furthermore, some representatives of the broader category of chemical and packaging industries as well as NGOs were present. In addition, several representatives from Member States Competent Authorities were also represented.

Missing uses, technical functions or products

No missing uses or technical functions were identified. In fact, the discussions suggested that a number of technical functions and uses that have been included in the use mapping were not relevant to PC 34, PC 23 and PC 18. The group was able to provide examples of technical functions and uses that could be excluded in order to focus the use map on the most relevant uses:

- Food and feed, fuel additives, fertilisers, and laboratory chemicals, could be taken out of the use map for PC 34;
- Adhesives could be taken out of the use map for PC 18;
- Plant protection products, paints and dry cleaning30 could be taken out of the use map for PC 23;
- Technical function as a heat transfer agent, embalming agent, corrosion inhibitor, and intermediate were seen as not relevant to the PCs in question.

It was noted that washing and cleaning products were relevant to leather articles since cleaning products are used for, e.g., leather sofas. When asked which technical functions were the most common ones, the participants noted that it was difficult to draw such conclusions without knowing which specific substances are registered for these PCs.

There is a need to verify that the data reflect the current situation – past experience of industry participants with the processing of REACH registration data suggests that a large proportion of uses can be eliminated as no longer relevant through industry surveys.

30 Dry cleaning uses solvents and solvents should not be used on leather.
Methodological challenges of the use map identified

The products/uses in the use maps are relatively broad and it may be useful to specify or disaggregate them. For example, inks can be used in pens but also in toner which is used in offices.

It was noted that in terms of the assessment of the impacts on companies, it is difficult to predict the future classification of chemicals, which is important for use maps for substances belonging to certain hazard classes (or future hazard classes).

The available data provide a better overview of the uses of mixture than of the service life of articles. There is also a large data gap with regard to imported articles.

Data challenges of registration data to be considered in the use map

There is a need for more detailed data to assess the potential impacts of GRA. In particular, the products/uses in the use maps are very broad and it would be useful to disaggregate them further than, for example, paper, textiles and leather.

It may not be possible to further develop the use maps just on the basis of REACH registration data. The limits of what can be achieved using REACH registration data have been reached.

Existing knowledge on articles potentially under the extended scope of the GRA

- Hazard classes potentially relevant for substances in your production processes

It was noted that in terms of the assessment of the impacts on companies, it is difficult to predict the future hazard classifications for specific substances. EDs was given as a clear example of uncertainty in the absence of harmonised criteria.

It was, however, noted that the companies that have tried to assess what proportion of their substance portfolio could be affected by GRA have arrived at the conclusion that this would be a very significant proportion.

It was noted that a wider industry survey across a large number of companies was needed since the impact could differ from company to company: for some companies, the share of substances affected could be 1%, for others 90%.

- Type of product or article

The participants discussed whether the presence in an article is a sufficient indicator of the need to act or whether the determination of a risk should be a precondition for acting. Exposure information is important to focus on uses with higher consumer exposure. For example, it was noted that, for example, tanning agents are by nature hazardous to the skin but this does not necessarily mean that there is a risk for professionals and consumers. Similarly, it was noted that some hazardous monomers may become harmless when processed into a polymer and the example of polyester dyes.

- Consumer use versus professional use

There was a wide agreement that there is a need for more clarity on the definition of professional use in terms of differentiating it from both industrial and consumer use. It was noted that one of the additional qualifiers for determining the use category could be the availability of training.
It was noted that, for example, consumers can buy haircare products aimed at professional uses (hairdressers) or that construction workers can be exposed as a result of both industrial and professional use.

It was noted that if further clarifications of the definition are provided for borderline cases, these will only help future registrations/revisions of registrations which may create a lack of consistency between past and future data.

Additional relevant data sources and stakeholders

- **Data sources**
  - Industry surveys
  - Use maps
  - SCIP
  - Poison Centre Notifications database
  - BREFs

- **Stakeholders**
  - Industry representatives
  - EuPIA: the European Printing Ink Association


The break-out group was mostly composed of petroleum, lubricant oils and chemical industry representatives. Some steel, metal working fluids and food industry representatives were also present. In addition, the group accounted for Member State Competent Authorities and national industry representatives.

The scope of break-out group 5 included numerous product categories. In Basket 1, the highest number of identified substances belongs to the hazard classes STOT RE 1 or 2 and CMR. The share of professional use differed very much across discussed PCs. While in PC 15, PC 31 and PC 38 the majority of substances were found in products for consumer use, in the other PCs the majority of substances were found in products for professional use. In terms of Basket 2, the majority of substances was identified in the hazard classes of endocrine disruptors and PBT/vPvBs.

The highest number of substances was found in PC 13 (fuels), but given that many components are classified with STOT due to aspiration hazards (chemical pneumonia) and CMR due to carcinogenicity, this PC was not discussed in detail. Therefore, due to the stakeholders’ interest and the high number of identified substances in PC 24 and PC 25 of Basket 1, the discussion in the group revolved mostly around the subject of lubricants oils, and metalworking fluids.
**Missing uses, technical functions or products**

Overall, based on an extensive discussion around PC 24 and PC 25, stakeholders found that the number of possible uses is overestimated. The discussion among participants indicated that the number of identified uses comes from the registration dossiers. Therefore, it was pointed out that it may occur that a registrant registers a higher number of uses than is effectively used, which may lead to the observed overestimation. Also, some of the substances identified in the mapping of uses can be indeed found in the application, but only at a very low level. For instance, in food industry, although many uses are listed, they refer mostly to areas where these substances are in contact with food but not in food itself. It was suggested that substances that are frequently used should be scrutinised in detail.

Consequently, the great number of uses has been seen as problematic in terms of readability of the use maps. It was suggested by several stakeholders that for clarity purposes the uses could be classified in broader group categories based on the commonalities. No data gaps were reported. However, stakeholders have indicated that individual use mapping were conducted by representatives of lubricants, metal working fluids and fuels sectors based on the ECHA guidance. It was noted that these use mapping did not investigate whether the identified uses would fall under the discussed GRA. In addition, it was highlighted that some use maps from individual sectors are published on the ECHA library and some of these might have updated SPERC background documents based on the format agreed in 2016. Thus, participants suggested that these parallel use mapping could be cross-checked in the present exercise.

Finally, the relevance of technical function was broadly questioned by participants. It was very unclear what would be the value added of this information.

**Methodological challenges of the use map identified**

As in previous groups, a key challenge for participants to contribute substantially to the discussion was related to the lack of specific list of substances that would be affected. It was clarified that this was due to confidentiality issues with some registration data.

The provided number of substances did not provide participants with any relevant insights. It was claimed that data on the tonnage for different uses, and/or concentration in the final products would be much more insightful. It has been pointed out that many companies try to avoid including substances in concentrations that would require classification of mixtures – for both consumer and professional uses – due to requests from their customers. Some participants noted that some mixtures, in particular metal working fluids, are delivered to the end-users as concentrated mixtures that would have to be diluted with water before the use, and asked how such concentrated mixtures would be addressed by the Commission in the future.

**Data challenges of registration data to be considered in the use map**

In terms of data challenges, two key elements were briefly discussed.

First of all, participants pointed out that it would be important to check the extent to which the reported data refer to unique number of substances concerned as some substances can be present in multiple hazard classes. In turn, such overlap could create a considerable overestimation.
Secondly, some stakeholders noted that the allocation to professional and consumer uses in registration dossiers had evolved over time. Given the considerable methodological improvements over the years, one needs to be careful when comparing this data.

**Existing knowledge on articles potentially under the extended scope of the GRA**

- **Hazard classes potentially relevant for substances in your production processes**

As indicated beforehand, it was difficult for industry representatives to estimate what are the hazard classes potentially relevant for substances in their production without having the access to the specific lists of substances. Participants shared the opinion that it would be helpful for such exercise, if the lists of substances would be shared with the sectors. Furthermore, participants suggested that information on substances in Basket 2 under investigation would help the industry to prepare for potential future substitutions. Nevertheless, the participants clarified that the industry does a continuous effort to identify the substances of concern on an ongoing basis. It was further specified that the replacement of some substances, especially in PC 24 is challenging. Therefore, in case some substances are included in GRA, the industry would need a considerable amount of time for substitutions (on average between 6 to 8 years).

- **Consumer use versus professional use**

When it comes to the classification of uses between consumer and professional ones, many participants questioned the practical application of such division. In the opinion of many, the use mapping should be more adequate and reflect the real situation. In fact, it was pointed out that some substances reported as consumer uses are in practice unlikely to be a use by consumers. It was suggested by some participants that technical function could be helpful in defining the borderlines between consumer and professional uses.

**Additional relevant data sources and stakeholders**

- **Data sources**
  - Individual use mapping conducted by representatives of lubricants, metal working fluids and fuels sectors;

12.3.6. Group 6 - PC 35: Washing and cleaning products; PC 4: Anti-freeze and de-icing products; PC 8 biocidal products

The break-out group was composed of companies and sector associations mostly representatives of cleaning and detergents products, fragrance and cosmetics industries. Furthermore, some representatives of the broader category of chemical and pharmaceutical industries were also present. In addition, a few representatives from Member States Competent Authorities were also present.

**Missing uses, technical functions or products**

Apart from the obvious errors (e.g. technical function = "service life of articles"), the participants did not feel legitimate to state that some TFs could be not relevant. The main reason for this is that an important part of the uses may not be known to the participants. Another reason is that the exercise seems difficult to carry out without knowing the substances concerned. Similarly, participants did not wish to state which should be the most relevant TFs or products. Most importantly for the impact assessment, no crucial information was noted as missing.
Methodological challenges of the use map identified

Participants found it difficult to understand the link between the use mapping and the impact assessment. The most common argument was that the impact may not be proportional to the number of substances: restriction on only one substance could have a huge impact, whereas restrictions on a group of many substances could only have a small one.

In general, the reasons behind an extension of the scope of GRA were not understood and supported: the reasons for a hazard rather than a risk approach were misunderstood; the extension could be understood as a systematic ban; investing in trainings for the protection of professionals should be preferred to the extension of GRA to professional uses, etc. As a result, the methodological challenges of the use map seemed to be of less importance.

Participants highlighted several issues related to overlapping regulations. For example, it was pointed out that restrictions on substances used in biocides (even if not as active substances) could have a significant impact on the market as they could jeopardize some biocidal product authorisations.

Potential conflicts were mentioned with regard to the Biocidal Products Regulation (BPR), Cosmetics and OHS. Some participants recommended that greater attention should be given to uses not covered by other legislations.

Finally, several needs for clarification were pointed out: how EDs (or PMTs...) were identified in Basket 2; the need for a clear definition of professional use; the need to distinguish some professional uses rather than to take all professional uses as a whole.

Data challenges of registration data to be considered in the use map

It was noted that registration dossiers certainly include obsolete data due to legacies which may not be relevant anymore. Conversely, potential gaps are expected since: (i) registrants might not be informed about all uses, (ii) downstream users may have not upstreamed actual uses, (iii) notifications by downstream users about their uses are not always included in registration dossiers.

It could be assumed that the two biases balance each other, but the participants had no information to support this assumption.

It has been mentioned that a use map considering tonnage bands would probably be enlightening, although the tonnages are not necessarily proportional to the issues. To put it differently, participants would have liked to see products and technical functions mapped according to tonnages, without denying that low tonnage substances could be of major importance.

In the same way, an exploitation of the “sector of use” data (independently of the possible product category) in the dossiers would be interesting.

Existing knowledge on articles potentially under the extended scope of the GRA

- Type of product or article

Participants did not specifically identify any items potentially affected by the GRA. However, some organisations referred to the Ricardo/Cefic study for which all available information was provided.

- Consumer use versus professional use

Concerning professional uses, all of them should not be considered the same way (e.g. analytical labs vs hairdressers). For a single substance, there may be different professional practices associated with different levels of protection, training, etc. Above all, it seemed
important to the participants to underline the need not to treat all professional uses as a whole.

Additional relevant data sources and stakeholders

- Data sources
  - Poison Centres Notifications: those would allow to get relevant data on actual uses compared to the expected ones. Nonetheless, legal obstacles could prevent access to that data. And no aggregated database is expected before 2025.
  - SCIP database: could provide some indications, although it is expected that the bulk of the data will be on substances outside the PC35, PC8 and PC4.

12.3.7. Group 7 - PC 39: Cosmetics, personal care products, PC 28: Perfumes, fragrances, PC 3: Air care products, PC 29: Pharmaceuticals

The break-out group was composed of companies and sector associations mostly representatives of the pharmaceutical and cosmetics industries. Furthermore, some representatives of toxicology and testing approach as well as NGO were also present. In addition, the group included a few representatives from the Member States Competent Authorities.

Given time constraints during this break-out group, most of the discussion revolved around the issues of general data, selected methodology as well as cosmetics products.

Missing uses, technical functions or products, Consumer use versus professional use

The participants underlined a general issue regarding the quality of registration data as a basis for assessing the impacts of the extension of GRA. A first potential bias mentioned was that some registrants may have ticked many uses and TF boxes by precaution to maintain access to potential markets. The registration data can also be to some extent outdated, and there was a concern expressed about the reliability of information on volumes declared in IUCLID. In general, several or even many TFs and uses appeared indeed not relevant to the PCs of the group and some participants expressed the need for further work to narrow down those lists. Some TFs could be missing but the general feedback was that there could be many non-relevant TFs (some examples were given, such as paints and inks or flame retardants, under cosmetics). On the other hand, some participants judged difficult to discard a given TF given the very high number of chemicals and associated functions in these PCs, out of which some are unknown to participants. Furthermore, one substance has in general uses in several PCs (e.g. one fragrance used in cosmetics and detergents). Generally, as in previous break-out groups, participants found difficult to relate TFs to a specific PC without knowing the identity of the substances concerned.

Regarding the data on professional and consumer uses, it was unclear for some participants whether raw registration data allow for a meaningful and reliable delineation of professional and consumer uses or not. It was pointed out that differences in interpretation of ECHA Guidance on registration can explain some of the unexpected results in the lists and repartition between professional and consumer uses.
Furthermore, it was noted that there can also be differences in the way registrants understand their product categories. In fact, each of the discussed PCs can have (sometimes significant) overlaps with other ones. For instance, fragrances can appear as products on their own, but can also be used in cosmetics or in detergents.

**Specific comments on PCs 3, 28, 29 and 39**

**Cosmetics (PC 39)**

Cosmetics represent a whole universe of chemicals within the chemicals industry. Hence, it is difficult to define the boundaries of this PC. There would be a need to work with refined product categories to understand functions and substitution (shampoo, lipstick...). The distinction made in the data between professional and consumer uses was surprising to some participants as their market is very similar.

**Fragrances (PC 28)**

The presence of CMRs and Respiratory sensitisers was considered as surprising since they are not allowed and are not used in practice, according to one participant. This same stakeholder noted that the number of CMRs 1A and 1B identified was beyond the 7 CMRs that industry itself has identified. A reference was made to an ongoing impact assessment by Ricardo performed by the sector.

**Air fresheners**

These products could have been difficult to define in a consistent manner across registrants since the category can cover products used on their own, or can be understood as fragrances.

**Pharmaceuticals**

Similarly to the case of fragrances, several participants were surprised by the presence of many CMRs. Their presence could be explained by the presence of their active pharmaceutical ingredients.

Difference between professional uses (by pharmacists, doctors) and consumers (patients) can appear as difficult to distinguish for pharmaceuticals, and therefore its usefulness and consequences for the further impact assessment are unclear.

**Additional relevant data sources and stakeholders and proposal for further impact assessment**

Many participants highlighted that the numbers of chemicals in TFs and hazard classes may not be the best proxy for actual uses, and future impact assessment of GRA costs and benefits. In particular, it was noted that at this stage only a few chemicals could drive the costs (e.g. costs). Using TF as a proxy was discussed in more detail as it was questioned whether substitution costs can be approached meaningfully using the functions. Subsequently, participants discussed how the impact assessment methodology would be developed given this issue.

To overcome the identified challenges, participants suggested to:

- continue to refine the work already done on use maps to check and narrow down the lists to what is significant for the impact assessment, by using available sectoral information (such as the Cosmling Database for Cosmetics) and cross-check with sectoral legislation that restricts or allows specific lists of chemicals such as the
Cosmetics Directive; continue applying common sense to remove those TFs that clearly do not correspond to a given PC;

- work under the framework of a Non-Disclosure Agreement with ECHA on a reduced and manageable set of most important chemicals for each PC;

- refer to the use maps elaborated by industry and submitted to ECHA.

Moreover, it was suggested to apply a weighting rate to the TFs, by referring to the number of times each has been mentioned by registrants.

Furthermore, it was suggested to disaggregate in further work on EDs from PBT/PV Bs that since this grouping does not appear to make sense (human health vs. environment).

It was also noted that GRA could reduce the number of chemicals that can be used, and therefore cause increased use and exposure to these chemicals. Even not being under the scope of GRA, alternatives to chemicals discarded because of the GRA can still have hazards. This should be assessed as potentially reducing the environmental and health benefits of implementing the GRA, according to the comment.

Another issue that was noted by one stakeholder was that the potential impact of GRA on animal testing should be assessed. This is because it would require, for chemicals that are already banned under sectorial pieces of legislation due to their harmonised classification, e.g., under the Cosmetics for their human health hazards, to generate additional data in order to verify whether they would be covered or not by the extended generic ban under REACH. It was pointed out that this would lead unnecessarily to more animal testing, contrary to what is desirable from the animal wellbeing perspective.

12.3.8. Group 8: Complex articles

One important consideration in the preparation of the workshop has been how far the impacts on the producers of complex articles will be represented in the development of the use maps based on registration data.

The incomplete information on products and technical uses already discussed in the workshop paper is considerably more relevant for the production of complex articles. Complex articles use very often many different substances and mixtures, meaning that assembling a complete data set on chemical compositions and risks is burdensome. At the same time, it is not clear whether registrants always know in which products or mixtures their substances are used due to the long value chains upstream and downstream. It was therefore decided to discuss these specific challenges in a distinct group on complex articles. This group aimed to understand how the approach of the use maps in respect to complex articles could be further developed to be useful in the impact assessment.

The break-out group was composed of companies and sector associations mostly representatives of aerospace, automobile and medical technology industries. Furthermore, some representatives of telecom, textile, and recycling industries as well as NGO were also present. In addition, the group included a few representatives from the Member States Competent Authorities.

Missing uses, technical functions or products

Participants discussed extensively how the information available could inform a prioritisation process for the introduction of GRA restrictions and which other information could support such a prioritisation process.
Most or all participants found it difficult to say which PCs are more relevant for their production processes than others in the context of the REACH Regulation. Dozens of PCs are relevant for manufacturers but many or most of them are used in the context of industrial use and are therefore not subject to the regulation in the same way.

Even though most complex articles are produced in industrial settings, very often, those products can be relevant for professional use (e.g. for repairs) and are also meant for use by consumers. Therefore, the precise definition of the use categories will be important for the assessment of impacts. An important product category to consider in this regard would be metals (PC7).

Many participants pointed out that the prioritisation process should focus first on consumer products due to the lack of options to secure a safe use for them. Professional uses also have different use profiles, with different needs. One example mentioned for this distinction was the textile sector where certain substances are needed for PPE in professional uses (e.g. hospital equipment, bullet proof vests).

Additionally, several participants stated that substances with ED properties should be an important focus point in the prioritisation process. The identification and assessment of those substances is not very advanced and thus should be promoted. This is also shown by their relatively low presence in basket 1 group of substances (already regulated) compared to the basket 2 group (under consideration) where they are one of the most important substance groups.

One participant pointed out that restricting specific substances in specific articles is already done (e.g. in fashion) and future restrictions could be introduced in a similar way following the results of the prioritisation process.

Some participants underlined specific considerations for their sectors:

- The CMR hazard class is less relevant in the discussion of GRA extension, as they are already covered. For metals, there is good data availability on releases to consumers in the use life which could provide important information for the prioritisation process.
- For metals and inorganics, the most important hazard category is CMR (if not already regulated) and skin sensitisers after close and prolonged contact. The metals industry is currently studying the relevance of metal emissions through analysis of sewage treatment plant data.
- Biocides are also an important area of consideration. While the professional use can ensure safe use conditions and many of the substances could also fall into potential essential use criteria, both considerations are less applicable for consumer use where both the essential use argument and the safe use argument are considerably weaker.
- Some uses are designed to avoid release of the chemical, while others are designed to release the chemical (e.g. tyres where the release is necessary to get the grip of the tyre). The risks of those very much differ and the methodology should take account of that.

Several participants also pointed out that finding the right information for the GRA introduction will also require a broader discussion on the GRA introduction that should in their view happen before the next workshop in June and should also be linked with the discussion on essential use.

Participants also asked for details on the future derogation system and what the timings and costs of the process would be.

The Commission underlined that it was necessary to distinguish between the relevance of specific considerations for particular sectors, and the prioritisation of certain hazard categories and uses in general, within the planned empowerment for the Commission. That
prioritisation would be discussed in general terms at the 23 March workshop and would eventually be developed into a work plan for restrictions. The assessment of impacts of potential changes to the derogation system takes place in another part of the project.

**Methodological challenges of the use map identified**

Some participants pointed out that the use of Article codes (ACs) instead of PCs would provide a far more relevant and accurate picture, especially for complex articles as using PCs as the basis for the analysis of complex articles breaks the REACH logic of articles and mixtures. The contractor explained that the reason for using this approach were the existing inaccuracies and gaps in the AC classification of the registration data.

Another participant pointed out that the principle of REACH "once an article always an article" (recently confirmed in a Court judgment) needs to be maintained also in the extension of the GRA approach. There should be consideration of defining the presence of hazardous substances as relating to homogenous materials, components or whole articles. A challenge for the assessment will be that the last or final article is very often a consumer article, while many interim articles before that are only used by professionals or even only in an industrial context.

It was also pointed out that, due to the existing restriction, information for CMR substances in textiles was available. However, this was not necessarily the case for other hazard classes. It was also necessary to consider how fixed the substances are in the garment.

Many participants asked how the use map information will be used in the impact assessment as, especially in regard to complex articles, many assumptions and uncertainties need to be considered. The risk that those assumptions would lead to the wrong conclusions was pointed out.

**Data challenges of registration data to be considered in the use map**

The participants confirmed that the key data challenge is the lack of knowledge of chemical companies (most of the registrants) on where their mixtures and articles are exactly used downstream. They also pointed out that this kind of data collection effort (both downstream and upstream) would require a legal requirement helping companies with the data collection.

Other participants also pointed out that somewhere in the production process of complex articles, mixtures and substances become articles, which changes the data collection requirements. At the production stage, where this happens, a significant amount of information is lost. So, gathering information for complex articles will require setting up new data collection infrastructure. Participants pointed out that data collection practices differ a lot in companies and that recommendations are needed to organise this in a more consistent way.

Additionally, many participants stated that the real impact on their companies can only be assessed if a list of substances to be regulated with their Chemical Abstract Service (CAS) numbers is provided. The whole chemical risk infrastructure is built in this way and even though participants acknowledged the problem that release of non-confirmed and confidential lists of substances might create unjustified market reactions, they highlighted that any definitive assessment and use mapping would be difficult without.

One participant mentioned dual use concepts as an important way to deal with articles where some parts might be subject to the regulation while others are not (e.g. similar to the ROHS Directive).

Additionally, some sector or company specific problems of data collection were mentioned:
• Medical devices are often very complex products. Data is available only in safety
data sheets and this is very limited. Collection of information in the value chain
requires considerable resources and long time frames.
• While large companies might have the resources and the heft with suppliers to ask
for data, small companies have not. Those small companies are also less likely to
provide data to the SCIP (Substances of Concern In Products) database. But the
requirements for such additional data collection for SMEs should not be
underestimated.

Existing knowledge on articles potentially under the extended scope of the GRA

Several participants mentioned that the use of data from the SCIP database for further
development of the use maps should be considered. They also pointed to the need to
prioritise the scope of the analysis first as the data set is very large.

Some Member States have done analysis that could support the use mapping. For example,
Denmark has published over 100 assessments on consumer products which collect a lot of
information on hazardous substances in consumer products.

12.4. Concluding remarks

12.4.1. Conclusions and discussions points

At the end of the break-out group sessions, the rapporteurs of each group presented the
main findings of the discussions. These findings were in line with the summary presented
in Section 3 and are not repeated in this Section.

The presentation of main findings from the break-out groups was followed by a questions
and answers session. Participants highlighted several elements to take into account during
the presentations of the break-out groups outcomes. For instance, some stakeholders
highlighted that environmental endpoints should not be forgotten in addition to the human
health ones regarding some substances, especially endocrine disruptors and PBT/vPvBs.
Moreover, stakeholders added that endocrine disruptors should be separated from
PBT/vPvBs in the use maps, especially regarding the human health and environmental
impacts of endocrine disruptors. Also, it would be critical to define professional use across
the different downstream users. Regarding the identification of the most important uses to
implement the GRA in a stepwise manner, stakeholders inquired about how the impact
assessment would carry out this exercise and quantify the data. The notion of safe use was
also brought forward as a key element that could be considered under GRA in the revision
of REACH.

One stakeholder asked if all professional uses would be regulated or only specific groups
of professional uses, relying on the example of laboratories at industrial sites, where it could
be difficult to assess whether the use was professional or industrial. Another stakeholder
stressed the risks of an increased level of animal testing following the implementation of the
GRA, as there would be a need to find substitutes for the phased-out substances. Several
stakeholders also highlighted the importance of predictability for industry, and the definition
of a reasonable timeline for phase-out allowing substitution to take place and possibilities
for derogations.

Regarding the impact assessment, the European Commission explained that it was aware
of the data gaps, that the assumptions of the analysis need to be transparently displayed
and that the impacts of those assumptions need to be taken into account. The role of
stakeholders is very important in providing the best possible estimates and supporting the
identification of the most relevant uses to then define the overall impacts. The idea is to obtain an overall assessment of the impact of the empowerment of GRA to present to the European Parliament and the European Council, as well as seeing what the likely impacts are. The approach would be to start with uses that are high on the priority list, including on the consumer side, then focusing on substances on their own, in mixtures and in articles and with a priority on mixtures based on hazard classes. Furthermore, a question was asked concerning the handling of uses already assessed as safe that will be under the GRA in the future, and whether derogations would be used.

Regarding safe use and essential use, the European Commission highlighted that the starting point of the GRA will be to focus on particularly hazardous substances and uses with exposure which is difficult to control. The discussion on safe use will be part of the following workshop on the 7th of June 2022. Concerning uses already assessed as safe, the continuation of the use will need to be considered in the framework of derogations as the GRA restrictions are implemented as generic bans. The need to derogate uses that are assessed as safe will be assessed in the on-going study on the reform of the authorisation and restriction processes. Concerning the question on professional uses, the European Commission noted that professional uses should be defined clearly and that this element is under discussion, including in the CARACAL-44 meeting on 23 March.

As for animal testing, the European Commission stressed that it is an important element to consider. However, it has to be assessed whether and how the restrictions would trigger more animal testing, as it is done upstream when looking at the authorisation requirements. In this regards, it was mentioned that the GRA is relying more on the precautionary principle.

Finally, the European Commission stressed that the results of the current exercise are extremely important to support the definition of implementation scenarios on which the assessment of impacts will be based. These implementation scenarios need to be structured in terms of timing of the implementation, as well as on prioritisation of different hazard classes and product types. This will also be discussed in the CARACAL-44 meeting on 23 March.

12.4.2. Next steps

The study team presented the next steps of the impact assessment, that will be built on consultations with stakeholders. Alongside the ongoing public consultation, a targeted survey for the industry and Member States will be launched in April. The study team will also organise focused interviews to understand current practices based on quantitative information. The last and fourth validation workshop will take place on the 7th of June.

At the next CARACAL meeting on 23 March, a Commission paper on the implementation of the GRA will be discussed. Furthermore, a joint meeting of CARACAL, the Advisory Committee on safety and health at work and its Working Party on Chemicals will take place on the 5th of April and focus on work protection and chemicals.

The impact assessment itself will be carried out following the Better Regulation Guidelines. Based on the work on the use maps and further information sources, a comparison of impacts between the baseline (the continuation of REACH as it is) and the extended implementation of the GRA will be made. This work will be integrated with the impact assessment work on the authorisation and restriction processes and the work on the criteria for assessing authorisations and restrictions (including the implementation of the essential use concept).

### List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AC</td>
<td>Article Code</td>
</tr>
<tr>
<td>BPR</td>
<td>Biocidal Products Regulation</td>
</tr>
<tr>
<td>BREFs</td>
<td>Best available techniques reference documents</td>
</tr>
<tr>
<td>CARACAL</td>
<td>Competent Authorities for REACH and CLP</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstract Service</td>
</tr>
<tr>
<td>CLP</td>
<td>Classification, Labelling and Packaging Regulation (EC) No 1272/2008</td>
</tr>
<tr>
<td>CMR</td>
<td>Carcinogenic, Mutagenic, or toxic for Reproduction (substances)</td>
</tr>
<tr>
<td>CSS</td>
<td>Chemicals Strategy for Sustainability</td>
</tr>
<tr>
<td>DUs</td>
<td>Downstream users</td>
</tr>
<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td>ED</td>
<td>Endocrine disruptors</td>
</tr>
<tr>
<td>GRA</td>
<td>Generic Risk Management Approach</td>
</tr>
<tr>
<td>IUCLID</td>
<td>Software to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.(^{34})</td>
</tr>
<tr>
<td>OHS</td>
<td>Occupational Health and Safety</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistent, Bioaccumulative and Toxic substances</td>
</tr>
<tr>
<td>PMT</td>
<td>Persistent, Mobile and Toxic substances</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal Protective Equipment</td>
</tr>
<tr>
<td>RoHS</td>
<td>Restriction of Hazardous Substances in Electrical and Electronic Equipment</td>
</tr>
<tr>
<td>SCIP</td>
<td>Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive</td>
</tr>
<tr>
<td>SR&amp;D</td>
<td>Scientific Research &amp; Development</td>
</tr>
<tr>
<td>STOT RE</td>
<td>Specific Target Organ Toxicity – Repeated Exposure (substances)</td>
</tr>
<tr>
<td>STOT SE</td>
<td>Specific Target Organ Toxicity – Single Exposure (substances)</td>
</tr>
<tr>
<td>SVHCs</td>
<td>Substances of Very High Concern</td>
</tr>
<tr>
<td>TF</td>
<td>Technical function</td>
</tr>
<tr>
<td>vPvB</td>
<td>very Persistent and very Bio-accumulative substances</td>
</tr>
<tr>
<td>vPvM</td>
<td>very Persistent and very Mobile substances</td>
</tr>
</tbody>
</table>

\(^{34}\) For more information, please see the ECHA website: https://echa.europa.eu/support/registration/creating-your-registration-dossier/what-is-iccid.
13.1. Executive summary

The European Commission, supported by the VVA Consortium, held an online workshop on the expected impacts of the extension of the Generic Risk management Approach (GRA) under the REACH Regulation on 27 June 2022.

The workshop was organised in the context of the planned reform of the REACH authorisation and restriction system based on the 2018 REACH Review\(^1\) and as announced in the Chemicals Strategy for Sustainability. The planned reform aims to build on positive experiences of implementing the REACH authorisation and restriction processes, while addressing current weaknesses and inefficiencies.

This was the last of four workshops on the topic and aimed to validate the first results of the impact assessment on the extension of the GRA, which will be integrated in the Commission’s Staff Working Document and inform the Commission’s decision. The workshop was organised in two plenary informative sessions, and one interactive session with four break-out groups discussing in parallel. In the break-out group discussions, participants were asked to provide feedback to the questions related to the expected impacts for “Human Health and Environment” (Group 1 and 2) and “Socio-economic Impacts, including impacts on the internal market, innovation and competitiveness of EU industry” (Group 3 and 4). The opening plenary session focused on the extension of GRA in the wider revision of REACH, the scope and overall approach to its impact assessment as well as providing the draft results of the costs and benefits of the extension of GRA. The closing plenary session summarised the findings from the break-out groups and outlined the next steps of the REACH revision.

The key discussion points during the workshop covered the following issues:

- The inclusion of professional uses in GRA could overlap with existing provisions dealing with the safety and health of workers at work (Directive 89/391/EEC – OSH) making them redundant.
- The Industry stakeholders noted that the assessment of impacts should consider that economic operators could react in different ways to GRA restrictions, depending on their sectors of activities and on the availability of alternatives. While in some cases substitution would be possible, in other cases the lack of alternatives would result in the end of activity for some operators.
- NGOs expressed concerns that the assumptions in the implementation scenarios, e.g. a selection of articles, and the possibility for minimal exposure derogations, are not in line with the commitments of the CSS.

**Break-out sessions on human health and environmental impacts**

The groups’ participants pointed out that, based on preliminary results, the human health impacts could be overestimated due to the existing risk management measures for workers, and/or to the use of substances at intermediary stages of production while not being present in the end product. Furthermore, the issue of endocrine disruptors and their impact on male infertility was raised. Industry stakeholders highlighted the possibility of duplication as this element was also covered within the reproductive toxicity hazard class. Also, the question of metals was brought up, as most of them belong to STOT and CMR. According to some participants, metals and their compounds need careful consideration as their hazard classification does not translate directly into health or environmental risk. Finally, participants questioned the relevance of respiratory sensitisers for consumers under the extended scope of GRA, as the exposure to this hazard class by consumers is limited.
Break-out sessions on socio-economic impacts

Based on the preliminary findings, some industry representatives raised their concerns about the limited granularity of the assessment arguing that some elements, according to them, were oversimplified. Some participants questioned the assessment being driven by the number of substances and tonnages pointing out these elements do not mirror well the economic effect of the ban on substances. This statement was underpinned by examples of sectors which use very low tonnage of some substances (e.g., medical devices). The ban on the relevant substances could result in substantial economic costs for the sectors. In addition, some participants pointed out that the impact assessment could underestimate the number and tonnage of substances that could be affected by the GRA. Hence, it was of great importance to participants to clearly state the assumptions made and existing uncertainties. Moreover, some participants highlighted that in their opinion the impact assessment assumes that all can be substituted, which is not correct. In case unsubstitutable substances were to be banned some products could disappear from the EU market. In addition, NGO representatives emphasised that clear signals to the industry were needed regarding the future modalities of the extension of GRA to ensure legal certainty and stimulate the development of new alternatives on the market.

In the closing session it was recalled that the consequences of chemical contamination are severe in the long run and hardly removable. Hence, the reform of the REACH is needed to protect the human health and environment from hazardous substances. It was highlighted that industrial uses should remain outside the scope of GRA, importance to have very clear justifications for what is included or excluded.

13.2. Introduction

13.2.1. General context and objective of the workshop

On 27 June 2022, the European Commission held an online workshop to validate the first results of the impact assessment on the extension of the generic approach to risk management (GRA) under the REACH Regulation to more hazard classes and uses, helping to guide the final report and inform the Commission’s process. This workshop was part of four events planned as part of the ongoing project “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction”. The first two workshops took place on 9 and 12 November 2021, targeting respectively Member State competent authorities and stakeholders from the industry and civil society and a third one on 21 March 2022. All three addressed the reform of the REACH Authorisation and Restriction processes.

The main objective of the workshop was to validate the results of the Impact Assessment following the third Workshop on 21 March 2022. Participants were invited to validate the estimates of the Impact Assessment of the extension of GRA with, as far as possible all costs and benefits linked to the planned reform.

The workshops are part of the wider consultations planned for the impact assessment of the revision of the REACH Regulation, which include a public consultation (from January to April 2022), along with targeted consultations in the form of questionnaires and follow-up interviews. Several contractors are supporting the European Commission in the impact assessment work. For the revision of authorisation and restriction under REACH, a specific study is being carried out by a consortium of consultants (VVA Consortium).
13.2.2. Workshop organisation

The workshop was held online on the Microsoft Teams platform. The agenda of the workshop is available in Annex 1 of this report.

The stakeholders were provided with a background paper (Annex 2) before the workshop that contained the relevant information on preliminary findings. After the opening plenary session, one round of break-out groups was organised, with four groups running simultaneously for around an hour. Break-out Groups 1 and 2 discussed human health and environmental impact of extending the GRA, whereas Groups 3 and 4 discussed socio-economic impacts, including impacts on the internal market, innovation and competitiveness on the EU market.

The VVA Consortium invited stakeholders to provide feedback on the cost and benefit of the extension of the REACH regulation concerning financial, human health and environmental factors. A moderator and a rapporteur were allocated to each of the break-out groups. A summary of discussions was reported back to the afternoon plenary session.

The afternoon plenary session summarized the findings of the discussions in the break-out groups and was followed by a short discussion on more general remarks about the impact assessment and the expected outcome of the consultation for the decision of the European Commission on the reform of REACH. The workshop was concluded with comments on the next steps.

13.2.3. Participants

The plenary sessions were attended by 350 participants, with 160 stakeholders registered to participate in the break-out group sessions. Various types of stakeholders took part as active participants in the break-out groups, including representatives of industry, consultancies, lawyers, industry associations, NGOs, public authorities and members of academia and research communities. The number of participants per type is presented in Figure 1 below.

![Participants by Stakeholder Group](image)

**Figure 1: Participants by Stakeholder Group**

13.2.4. Summary of the introductory session

[European Commission] opened the workshop introducing the context of the REACH reform and the workshop’s objectives. He reminded the participants that the extension of the GRA to new hazard classes and to professional uses aims at speeding up substitution of the most harmful chemicals through
amendments of the REACH Regulation. This fourth and last workshop was part of the study aiming at assessing the impacts of the extension of GRA with, as far as possible, all costs and benefits linked to the planned changes.

It was highlighted that the implementation of new GRA restrictions would take place in a stepwise manner. For the impact assessment, three different implementation scenarios are assumed but the concrete transition pathway for the chemical industry to a green and digital economy is currently being elaborated in co-operation with the concerned industry.

The workshop aimed to validate the calculations and assumptions that were taken for the impact assessment of the GRA extension. The assessment included the benefits of a faster substitution (better protection of human health and the environment), as well as the costs for industry and public authorities.

Following the welcome address, VVA presented the objective and the technicalities of the workshop and 3G GROW presented the role of the GRA extension in the wider context of the REACH reform and parallel technical studies being assessed simultaneously. For instance, he noted that the costs and benefits of the GRA extension would interact with changes associated to the introduction of the ‘Essential Use Concept’ (ESU), particularly around the potential for derogations.

Following the introductory speeches, VVA provided a brief overview of the scope of the impact assessment. Its overall approach including three potential implementation scenarios as presented in Table 1 below, and its possible limitations (the details are presented in Annex 1, Section 1.2 and 2.2).

<table>
<thead>
<tr>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer uses</td>
<td>All</td>
<td>All</td>
</tr>
<tr>
<td>Professional uses</td>
<td>Selection of uses by professionals at the same time as uses by consumers</td>
<td>All uses by professionals, after uses by consumers</td>
</tr>
<tr>
<td>Hazard classes</td>
<td>All at the same time</td>
<td>Stepwise implementation</td>
</tr>
<tr>
<td>Hazard categories</td>
<td>Only category 1</td>
<td>Only category 1</td>
</tr>
<tr>
<td>Product type</td>
<td>Restriction of substances on their own and in mixtures; Then, all article types</td>
<td>Restriction of substances on their own and in mixtures and in parallel restriction of selected article types</td>
</tr>
</tbody>
</table>

It was decided that based on the extension of GRA, the European Commission would be empowered to introduce restrictions under Article 69(2) for substances meeting the following hazard properties:

- Endocrine disruptors (ED) with effects for human health;
- ED with effects on the environment;
- Persistent, bioaccumulative and toxic substances (PBT);
- Very persistent and very bioaccumulative substances (vPvB).
- Substances with specific target organ toxicity, single exposure (STOT SE);
- Substances with specific target organ toxicity, repeated exposure (STOT RE);
- Immunotoxic substances;
- Neurotoxic substances;
- Respiratory sensitisers

A possible extension of GRA to persistent, mobile and toxic (PvMT) substances and very persistent and very mobile (vPvM) substances is still under discussion, but it is considered in the assessment of impacts. As mentioned earlier, the implementation of GRA restrictions would take place gradually, as a stepwise manner along with a clear work plan to provide clarity and predictability to all stakeholders. In line with the current practice, restrictions for substances on their own and in mixtures would be prioritised.

The VVA Consortium presented the assessment of the estimated economic impacts for the industry. It was specified that while the CEFIC study estimated the impact of GRA in terms of turnover losses, the VVA Consortium opted for using the profit losses considering it was a better indicator for changes in producer surplus. Loss of turnover is an immediate impact on the affected industries, but it does not represent a net loss to society. Three data sources were used in the VVA assessment to estimate the costs using the two indicators: number of substances and tonnage, or substances (for more details please consult Annex I, Section 3.1.2).

The last speaker of the opening plenary session was VVA Consortium presenting the assessment of human health and environmental impacts of the GRA extension. The benefits are expected to arise from a reduction in exposures of people and the environment to the most harmful substances (e.g., therefore reduction of future cases of disease and/or environmental damage). Because of the limitations in the availability of data, the methodology followed is determining a break-even point, i.e., how large the benefits need to be for the GRA extension to pass a cost-benefit test for human health and environment (details provided in Annex I, Section 3.1.3). Although it was recognised that this does not correspond to the ideal model to assess the human health and environmental impacts, it is the most suitable approach given the data available.

It was clarified that the approach to quantifying and monetising the benefits involved:

- Estimating how many substances are identified and classified for the relevant hazard classes and use categories;
- Identifying the disorders, diseases and impacts that are associated with each of those hazard properties;
- Applying appropriate economic metrics for the single cases avoided or units of environmental area improved for each type of hazard properties (in €); and
- Estimating the number of cases of these diseases, disorders and impacts that would have to be reduced in order for the expected benefits of the GRA extension to outweigh the costs.

Following the presentations, the floor was opened to questions and answers (Q&A) from participants. The following issues and questions were raised in the Q&A session.

- Many stakeholders believed that the undertaken approach was pragmatic and sensible given the data limitations.
- The importance of enzymes was pointed out by a national competent authority and their inclusion under the scope of extended GRA would have substantial costs for the industry.
• An industry representative questioned the approach of using changes in profit as an economic indicator. Clarifications were requested on the number of substances, differing significantly from the number estimated in the Cefic study, and how the assumptions on the affected substances were made.

• Some stakeholders asked how the estimated impacts may differ between different SMEs, as the impact would vary from one sector to another.

• Several stakeholders pointed out that the extension of the GRA to professional users would be one of the most significant and impactful change under the ongoing reform. Expected costs of restricting professional uses are considered significant.

• Many stakeholders highlighted that not all of the substances subject to restriction can be substituted and that this should be reflected in the assessment. Some of these substances have specific properties for which they are used in dedicated processes and that would be lost due to the restrictions (e.g., uses in medical devices, recycling process).

Several elements were also questioned by NGO representatives:

• If derogation were to be allowed for minimal exposure, this would mean allowing some uses considered as non-essential and would contradict the ambition of CSS.

• The presentation seemed to indicate that Article 68(2) restrictions would only apply only to substances with harmonised classification under CLP, while the current legal text in Article 68(2) applies to all CMRs that meet the criteria.

• In the assessment, it is assumed that alternatives would be more expensive, which is not always necessarily the case.

• The willingness to pay approach as method to assess the benefits was criticised because it can create bias depending on the economic situation of the agent. According to the OECD, the willingness to pay tends to be lower than the willingness to accept compensation, and therefore underestimates the benefits.

• Pointed out that several data sources (including the CEFIC study) are used for the assessment and triangulation was necessary for robust results.

• Answered the questions regarding the number of substances included in the assessment. In particular he noted that this is based on REACH registration data, divided into two baskets. Basket one includes substances with confirmed hazard properties, while in the basket two there are substances still under assessment. There is a higher uncertainty on the hazard properties of substances in basket two, and this basket is much larger.

• Answered the questions regarding the cost estimates. The indicator for the economic assessment is lost profit, which takes into account that if the production will stop, no production costs will be incurred either. However, if there is time to adapt to the new situation those profit losses might be lower as the production can be adapted. The overall costs will be strongly influenced by derogations as those will focus on substances where restrictions would cause high costs and low benefits.

• Agreed on the shortcomings of the willingness to pay approach, whereas the willingness to accept compensation represents a more useful tool. This will be taken into account in the assessment, where possible. Furthermore, regarding environmental damage, costs linked to the remediation of contaminated sites will be considered. Additionally, _________ treasured his agreement with _________ that this impact assessment is to be understood as a model and thus a simplification of reality. It should be noted that even though the assumptions might have been broad this did not necessarily invalidate the model as incorrect.
13.3. Break-out groups

This section introduces the key points that emerged from the discussions in each of the four break-out groups. To help participants prepare the discussion a workshop paper including the break-out groups’ discussion questions was shared in advance with the participants (Annex 2). The aim of the workshop and the break-out groups was to discuss the approach and first estimates of the costs and benefits of each of implementation scenarios. One round of the break-out groups was organised, with four groups running simultaneously for around an hour following the first plenary session:

**Break out Groups 1 and 2 discussed Human Health and Environmental Impacts of the different options for extending the GRA, focusing on the following questions:**

- Is the overall approach to estimating the human health and environmental impacts suitable or an alternative method should have been used?
- Are the population attributable fractions used for the comparison — 1%, 2.5% and 10% — reasonable? Should the central PAF be lower or higher? Are the lower and upper bounds adequate to capture uncertainty?
- For the evaluation of the benefits of restricting EDs with human health effects, have the right health outcomes been selected? What other health outcomes should be considered?
- For the hazard class STOT, what health outcomes should be considered for the evaluation?
- For respiratory sensitisers, the team is considering asthma as the most relevant health outcome? Should we consider any other health outcome?

**Break out Groups 3 and 4 discussed socio-economic impacts, including impacts on the internal market, innovation and competitiveness on the EU market, focusing on the following questions:**

- Is the overall approach to estimating the scale of economic costs clear and logical, given the current uncertainties?
- Do the anticipated effects e.g., number of substances and affected tonnages, appear realistic, based on any preparatory analysis you have undertaken?
- Have you identified — or are you able to identify — any key product functionalities that may be affected by the GRA? What would be the effects? Could examples be provided?
- What further information on potential implementation scenarios or substance prioritisation criteria, for example, would be helpful?
- What advantages may occur as a result of the GRA? For example, greater clarity on regulatory decision making, stronger incentives for innovation, collaboration? Would this result in any business opportunities?
- What about specific costs and benefits to Small and Medium Enterprises (SMEs)? Do they require specific support and/or mitigation measures?

Each breakout group, on average, was composed of 30-40 participants. The following summaries combine the feedback of both groups on each topic, although not all topics were discussed in both groups.
13.3.1. Group 1 & 2: Human health and environmental impacts

The two break-out groups on human and environmental impacts were composed of representatives of industry covering a wide range of sectors, national authorities, ECHA, NGOs and researchers. Overall nearly 80 participants took part in the discussions (40 in each group).

The discussion followed the structure of the questions provided beforehand in the Workshop Background Paper. The participants discussed various and broad aspects of the methodology used and first relevant results, and it was not possible to distill a common view from the discussions, only points and issues to consider in the finalisation of the analysis.

1. Is the overall approach to estimating the human health and environmental impacts suitable or an alternative method should have been used?

On the general methodology the following points were discussed by participants:

- Several participants found the proposed approach (i.e. break-even analysis) pragmatic and sound, given the lack of data.
- Several participants pointed out that it is important to clearly document the evidence used to assess the health and environmental impacts. As pointed out by the consultants, the evidence for different health outcomes and the link to the hazard classes under consideration was not uniformly good. The final report should clearly mark the evidence used and its quality.
- The workshop report came too late in the process and the time to review it was too short to allow a proper assessment of the methods and data sources. This needs to be ensured in the final report.
- Some participants pointed out that banning a substance can have significant indirect negative impacts on environmental protection goals or indirect health impacts if the substance is used in medical devices or other health relevant areas. These effects need to be considered too.
- Several participants asked about the assumptions on the environmental and human health impacts of substitutes and how those are taken into account. To avoid regrettable substitution these effects need to be clearly spelled out.
- Mixture effects need also to be considered.
- Participants also pointed out that the use of categories (professional, consumer and industrial) need to be clearly defined to be workable.
- The human health effects could be overestimated due to the current use of risk management measures for workers. In case those are efficient, the gains will be considerably smaller. Another reason for such an overestimate especially for articles was mentioned for intermediate substances which are used in the production but are not part of the final product (Chromium(VI) and its hazardous oxidated forms were mentioned that are not part of the final product).
- Some participants questioned why PMT chemicals were not specifically mentioned in the approach.
- Background exposure needs to be taken into account too for natural occurring substances, e.g. metals. This background exposure can be very different for different substances and hazard classes (again for metals this is particularly relevant).
• Some participants also urged to check whether metals were included when estimating environmental impacts of PBTs (they do not undergo PBT assessment). A related question was also about PBT substances which are not named in the report.

• The cost of remediation could be an important methodological addition to the analysis of the environmental impacts. Moreover, it was suggested that a certain fraction of the costs for treatment could be attributed to chemicals in similarity to the population attributable fractions for diseases (cf. below).

• Another point mentioned were exposure thresholds. Most chemicals are toxic from a certain level onwards, while many, under certain thresholds, are safe to use. This needs to be considered in the analysis of human health and environmental impacts.

• It is also very important to look only at substances that can be efficiently restricted as they are used on purpose (in fact, some chemicals can be found in the environment, but they are never used and would be hard to restrict).

2. Are the population attributable fractions used for the comparison — 1%, 2.5% and 10% — reasonable? Should the central PAF be lower or higher? Are the lower and upper bounds adequate to capture uncertainty?

On the discussion of population attributable fractions (PAF), the following issues were mentioned.

• Several participants pointed out that the evidence used on the PAF need to be clearly set out and documented as it will be uncertain and of various quality.

• It was also discussed that workers legislation and its safety measures are clearly relevant for the size of the PAFs and need to be considered. For that purpose the distinction between professional and consumer use is very important.

• The comments on the scale of the used PAFs were very diverse. Some participants thought that the used PAFs were too low while others said they could be too high. It was pointed out that the GRA for CMRs could provide good insights as the effects are well documented for this hazard class.

• Some participants have knowledge of “cost of inaction” studies and think they should be taken into account in the assessment⁶.

3. For the evaluation of the benefits of restricting EDs with human health effects, have the right health outcomes been selected? What other health outcomes should be considered?

Part of the discussion focused on Endocrine Disrupting substances, covering the following main points:

• For the mentioned health effect on male infertility there is the danger of duplication as this health outcome is also covered by the reproductive toxicity hazard class.

• Endocrine disruptors are also important for the assessment of environmental impacts and the approach to those impacts has been not discussed in detail in the workshop paper.

• Several participants found that the results will be very dependent on the health outcomes chosen for the analysis and therefore it is important that the health outcomes are chosen based on a robust methodology and that the evidence to test the relevance of the health outcomes is robust.

4. For the hazard class STOT, what health outcomes should be considered for the evaluation?

Concerning STOT, the following remarks were made:
• Many metals are both STOT and CMR which could be another reason for duplication.
• For STOTs the difference between single and repeated exposure is very important and related to the distinction between professional and consumer use as professionals fall more often in the repeated exposure category while consumers more often in the single exposure category.
• Neurotoxic effects were mentioned as important health endpoints to be considered. Another endpoint mentioned was chronic liver disease. But for both endpoints the available data is not yet very robust. Data is generally lacking for STOTs, which will hinder any quantitative assessment.

5. For respiratory sensitisers, the team is considering asthma as the most relevant health outcome? Should we consider any other health outcome?

The last part of the discussion focused on respiratory sensitisers.
• Participants questioned whether the hazard class was relevant for consumers as the exposure was thought to be very limited.
• Possible overlap was mentioned as many substances are both STOT and respiratory sensitisers.
• A study by the university of Sheffield was mentioned, as it had a very good approach to identify the relevant health outcomes.
• COPD (Chronic Obstructive Pulmonary Disease) was mentioned as a second relevant health outcome for the respiratory sensitiser hazard class in addition to asthma.

13.3.2. Group 3 & 4: Socio-economic impacts, including impacts on the internal market, innovation and competitiveness of EU industry

The two break-out groups were composed of around 40 participants each with representatives from industry, consultancies, NGOs, and public authorities.

In general, the following aspects were highlighted in the discussions as important elements for the assessment of socio-economic impacts:
• The use of tonnage to capture the effects can be problematic as it might not adequately capture the effects on the supply chain and the overall extent of the effects;
• The number of substances and tonnages that could be affected by the GRA are too small;
The importance of derogations for the implementation and the clarification of the concept of essential use.

6. Is the overall approach to estimating the scale of economic costs clear and logical, given the current uncertainties?

An industry representative commented positively on the overall methodological approach of the impact assessment. In view of the great complexity of the task and related uncertainties, it is important to present transparently the assumptions made and to subject them to extensive sensitivity analyses. Other participants from companies and industry associations expressed their concerns about the granularity of the analysis. In particular, they voiced the fundamental concern that the analysis is over-simplified. In this respect, the following remarks were made:

- The focus on the number and tonnage of substances does not adequately reflect ripple effects in supply chains, which are shaped by the cascade effect of one substance, many mixtures, countless products. Such effects can also negatively affect innovation. The fact that certain functionalities are (or can be) lost due to the ban of some substances can have a more serious impact on the production of articles than what the pure analysis of the substance would suggest. This is especially the case of indirect effects, if the substance itself is not used in the supply chain, but the use is indispensable upstream. As a result, effects that would also be important for the assessment are not taken into account, such as loss of performance (e.g. protective gear was mentioned, product lifetime and the associated increased resource and/or climate impact, etc.).

- Tonnage is only a limited approximation of the extent of effects. This is especially true for certain sectors that (have to) use a high number of different substances and/or use some substances only in small quantities. These tend to be strategic uses, for which substances are difficult to substitute or the substitution timeline would be much longer than the average six years timeline assumed in the cost assessment. Examples mentioned were:
  - the medical devices and diagnostics sectors, which use low tonnage and high number of substances and where the substitution of substances is limited by the need to comply to sector-specific legislation;
  - the aerospace and the medical devices sectors, for which the assumptions on the average substitution period were considered clearly too short and the percentage of feasible substitution clearly overestimated;
  - the substance group of enzymes (respiratory sensitisers), which shows that there is not always a correlation between tonnage and magnitude of impacts. One participant considered that a ban on enzymes, which are only used in small quantities, would have a significantly higher average unit cost than EUR 6 million considered in the analysis. In addition, further indirect effects of such ban should be considered, e.g. massive use of surfactants in the area of detergents and cleaning agents, the need to increase washing temperature, etc.
  - Substitution costs were also considered high for metals.

- Industry representatives unanimously expressed concerns about the assumption in the analysis that all substances are in principle substitutable. It was clearly pointed out that this would certainly not be the case for all uses and that if such substances were restricted, the market could be expected to disappear unless derogations were made. Also, the cost of alternatives could increase significantly and/or their reduced availability if the demand of such alternatives increases significantly. However, NGO representatives disagreed with these concerns and noted that the most important
factor is to provide clarity to industry on what the extension of GRA will entail. Only such legal certainty would pave the way for the development of alternatives, as there would be a clear market perspective for these alternatives for the period after the end of use and the development effort could thus be justified. NGO representatives also noted that some of the concerns raised by industry representatives would be addressed by derogations for essential uses.

- Industry representatives from the colours and paint sector noted that the indirect costs should also be considered, i.e. for both for the upstream suppliers and the downstream users. Also, compliance costs seem to be missing, e.g. for testing trace substances; such costs were high in previous restriction dossiers.
- Substances are sometimes used in several mixtures, which could have an impact on cost estimates.

7. Do the anticipated effects e.g. number of substances and affected tonnages, look realistic, based on any preparatory analysis you have undertaken?

Some participants expressed the general opinion that the number of substances and tonnages that could be affected by the GRA were too small. Particularly concerns were expressed with regard to the accuracy/representativeness of the tonnage data, and it was considered especially important to clearly explain the assumptions made to derive the tonnages, to discuss uncertainties and undergo appropriate sensitivity analyses.

Specific questions raised in this context were:

- Presentation of the basis for the number of PMT substances and further contextualisation with regard to their role in a future extension of GRA;
- Dealing with tonnage bands (especially > 1000 t - here a problem could lie in the use of the registered tonnage);
- Bundling the effects of restricting substance with different hazard properties (PBT, vPvB, etc.) was viewed critically and an individual consideration was suggested.

It was also suggested to include possible negative effects on human health and the environment that could result from the ban of substances and the related loss of performance or functionality (see above). Interactions with other EU sustainability goals in the areas of climate, circular economy or product policy should also be taken into account.

8. Have you identified – or are you able to identify – any key product functionalities that may be affected by the GRA? What effects would result? Could examples be provided?

Overall, according to company representatives, it was difficult to give concrete answers to questions on the specific impact of individual products or product areas, as no concrete lists of substances were communicated within the framework of the impact assessment activities with which the company's own portfolio could be compared. Nevertheless, some examples were given, such as enzymes (see above), highly reactive substances in the field of polymer chemistry, which lead to stable polymers and thus to a long life of products made from them, chemicals that are needed for the production of pharmaceuticals (or in similar fields, e.g. certain solvents).

Substances that are important for the long-term safety of products were also mentioned (e.g. stability and durability of tyres). Areas where alternatives are currently lacking should also be excluded (leather tanning linked to some CMRs that are not substitutable, some citrus-based essential oils in the fragrance industry).
9. What further information on potential implementation scenarios or substance prioritisation criteria, for example, would be helpful?

Concerning the implementation scenarios, participants emphasised the importance of derogations. Participants pointed out that at the moment it is not sufficiently clear how the concept of essential use will be developed and applied in the context of the GRA. Industry representatives also emphasised that further derogations might be needed to allow non-essential uses, provided they lead to minimal exposure of humans and the environment. It would also help if the impact assessment were to look at uses more in terms of exposure levels in order to identify areas where more action is needed due to high exposure.

It was also noted that the implementation scenarios also depend heavily on the concentration limit at which a GRA restriction comes into force. This relates to the concentration thresholds in the product (0.1% has often been used in the past), but a question was raised on whether the tonnage of the substance used would also play a role (e.g. if GRA restrictions would only apply for substances used above 1 tonne per year, or to the first gram, analogous to the current authorisation system). These aspects have not yet been developed, but can influence the expected impacts significantly.

10. What advantages may occur as a result of the GRA? For example greater clarity on regulatory decision making, stronger incentives for innovation, collaboration? What business opportunities might result?

An NGO representative disagreed with the perception by industry representatives that the impact on the economy was greatly underestimated. When REACH was first discussed and adopted, unacceptably high impacts on the economy were often predicted by industry, but these did not materialise to the same extent, or the industry showed extraordinary resilience and was able to adapt to the new conditions, gaining market strength and creating innovation. In their view, it is not accurate to consider that there would be a loss of quality in all cases and that such loss of quality can often be compensated for by further product development. Industry representatives noted that ultimately the effects depend strongly on the respective sector.

With regard to possible socio-economic benefits, some participants were rather cautious and expressed concern that in some areas there might be a tendency to abandon economic activities. This is particularly feared if the subsequent implementation of the GRA provides that a new CLP (inclusion in Annex VI of the CLP Regulation) could directly lead to the substance being restricted. Therefore, it was emphasised that possible adverse effects should be taken into account. It was also stressed that a much more hazard-based approach such as the GRA would undermine processes in other areas, such as food contact materials (other examples were medical products, cosmetics, etc.).

It was emphasised that a possible opportunity of the GRA could be to simplify the processes and also to reduce the administrative burden (especially for authorities). Environmental and human health effects are also viewed positively if a balance can be found between a total ban on all substances and a sensible reduction in exposure. In the end, however, participants also said that the real costs could not be modelled and would only become visible in 20 years.

11. What about costs and benefits to Small and Medium Enterprises (SMEs) do they require specific support and/or mitigation measures?

An industry representative pointed out that a large proportion of mixtures containing substances within the possible scope of the future GRA are used by professional users and only to a lesser extent (in terms of employees) in industrial settings. A very large proportion of these professional users are employed in SMEs. He further clarified that the technical capacity of SMEs is very limited and these companies rely often on other market actors to
find alternatives to banned substances. In particular, SMEs should be able to buy products on the market for which there is legal certainty (also in the long term), so that the basis for business is given in the long term. In this context, it was emphasised that the term ‘professional use’ should be defined and it should be clarified what professional uses should ultimately be covered by the G RA. For example, one participant noted that car repair shops were classified between professional and industrial activities in an ECHA report from 2020, and in such cases further clarification would be required.

However, legal certainty alone will not be sufficient unless the future legislation is designed in a way that it is feasible for SMEs. It was emphasised that innovation, in the sense of substitution, should be regarded as a less realistic scenario (which does not mean that SMEs among chemical manufacturers in particular cannot also be innovative in alternatives development).

At the same time, derogation processes must also be designed in such a way that SMEs can make use of them. A highly technical process, such as the current authorisation process, or even participation in the restriction process, which is usually not carried out in the national language, create insurmountable hurdles for SMEs and, in the representative's opinion, are more likely to lead to a cessation of business in the affected areas than to adjustments. Other technical and economic issues, such as the lack of testing methods or their high cost and evaluation methods for alternatives, are also causing a high burden for SMEs.

Participants also referred to studies by two sector associations. The first study by IFRA - Fragrance sector stated that 50% of the turnover in the sector is generated by SMEs and that the introduction of the G RA could lead to a net market loss of 15% and an additional regulatory burden of 4%. The other study, conducted by AISE (International Association for Soaps, Detergents and Maintenance Products), found that SMEs were underrepresented in the study, but there is anecdotal evidence that 75-100% of products in this sector could be affected by G RA. Ultimately, however, this study lacks the granularity to confirm these assumptions.

13.4. Concluding remarks
13.4.1. Afternoon session

The afternoon plenary session following the break-out groups’ discussions was moderated by [OG GROW]. [ippo presented the findings of Group 3 and 4 on socio-economic impacts, while [ippo presented the findings of Group 1 and 2 on health and environmental impacts.

During the discussion, it was highlighted that industrial uses should definitely be kept outside the scope of the G RA and that special attention should be paid to this issue, which highlights the importance to have very clear justifications for what is included or excluded including some evaluation of quality of the data behind it.

Another note was that metals and their compounds should not be included in the category vPvB/PBTs. Also, it was pointed out that essentiality concept will useful to avoid the removal of high hazard substance uses which have an overall beneficial effect upon for

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example climate impacts. In most cases, because of the substitution timelines, companies would need to begin work on alternatives long before essentiality was confirmed.

13.4.2. Conclusions and next steps

Overall many participants acknowledged the complexity of the analytical task and pointed out that the effort of the consultants was pragmatic and robust. Other participants highlighted many uncertainties and required assumptions to well take limitations into account.

All the inputs were noted and will be incorporated to the extent possible in the impact assessment to validate and extend the findings. Further studies are being conducted simultaneously and will also contribute to the design of the REACH revision. Further discussions on the reform of authorisations and restrictions will take place during next CARACAL meeting on 6th of July 2022. The Commission impact assessment is expected to be finalised in autumn 2022 and the Commission proposal by the end of 2022, or beginning of 2023.
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