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

Stakeholders' workshop report

21 March 2022

EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
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Workshop on the extension of the generic approach to risk management under the REACH Regulation

Workshop report

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

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LIST OF ABBREVIATIONS

AC	Article Code
BPR	Biocidal Products Regulation
BREFs	Best available techniques reference documents
CARACAL	Competent Authorities for REACH and CLP
CAS	Chemical Abstract Service
CLP	Classification, Labelling and Packaging Regulation (EC) No 1272/2008
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction (substances)
CSS	Chemicals Strategy for Sustainability
DUs	Downstream users
ECHA	European Chemicals Agency
ED	Endocrine disruptors
GRA	Generic Risk management Approach
IUCLID	Software to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.[1]
OHS	Occupational Health and Safety
PBT	Persistent, Bioaccumulative and Toxic substances
PMT	Persistent, Mobile and Toxic substances
PPE	Personal Protective Equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
SCIP	Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive
SR&D	Scientific Research & Development
STOT RE	Specific Target Organ Toxicity – Repeated Exposure (substances)
STOT SE	Specific Target Organ Toxicity – Single Exposure (substances)
SVHCs	Substances of Very High Concern
TF	Technical function
vPvB	very Persistent and very Bio-accumulative substances
vPvM	very Persistent and very Mobile substances

[1] For more information, please see the ECHA website: https://echa.europa.eu/support/registration/creating-your-registration-dossier/what-is-iuclid-

1. EXECUTIVE SUMMARY

On 21 March 2022, an online workshop was held 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[2] and as announced in the Chemicals Strategy for Sustainability (CSS). The planned reform aims to build on the positive experiences in implementing the REACH authorisation and restriction processes and address their current weakness and inefficiencies.

The main objective of the workshop was to present the first results and assumptions made on uses of the most harmful substances that may be subject to GRA in the future. Participants were invited to critically review the information extracted from the REACH registration data and the use maps prepared based on that data, and validate it and complete where necessary. At the later stage, the developed use maps will serve as a basis for assessing 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 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 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 5 - PC 24: Lubricants, greases, release products, PC 25: Metal working fluids, PC 31: Polishes and wax blends, PC 15: Non-metal-surface treatment products, PC 16: Heat transfer fluids, PC 17: Hydraulic fluids, PC 13: Fuels, PC 14: Metal surface treatment products, PC 38: Welding and soldering products, flux products
- 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 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 substances has been assigned to certain uses could help refine the use map.

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

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN

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 use and from consumer use.

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

2. INTRODUCTION

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 to map the uses that would be impacted by the extension of GRA and discuss those with stakeholders. Participants were invited to question and validate the approach taken on the use maps and to complement and correct the data gathered so far. At a later stage, these developed use maps will help 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 in 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 9 and 12 November 2021, targeting respectively Member State competent authorities and 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, 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 consultancies (VVA Consortium).

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 background paper (**Annex 2**) that contained the relevant information for the discussions. After the **opening session**, **two rounds of the break-out groups** were organised, each running for around an hour and a half. The first round took place in the morning and the second round in the afternoon.

The VVA Consortium invited stakeholders to provide feedback on the use maps across eight dedicated break-out groups. Participants were asked to register for the group of their preference subject to available places. 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 5 -** PC 24**:** Lubricants, greases, release products, PC 25: Metal working fluids, PC 31: Polishes and wax blends, PC 15: Non-metal-surface treatment products, PC 16: Heat transfer fluids, PC 17: Hydraulic fluids, PC 13: Fuels, PC 14: Metal surface treatment products, PC 38: Welding and soldering products, flux products
- **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 all registered participants, the break-out groups were accessible only to the participants who registered as active[3].

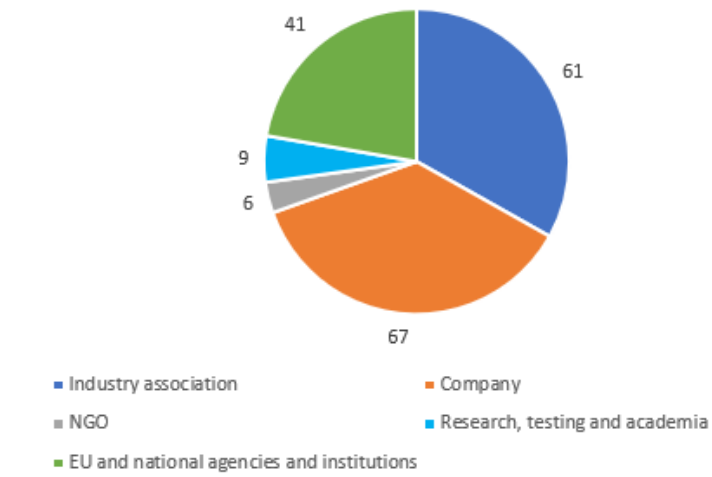
Finally, the participants were invited to submit their **written contributions** to the VVA Consortium by email (REACH_WORKSHOP@vva.it) by 8 April 2022.

2.3. Participants

The online opening and closing sessions 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 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.

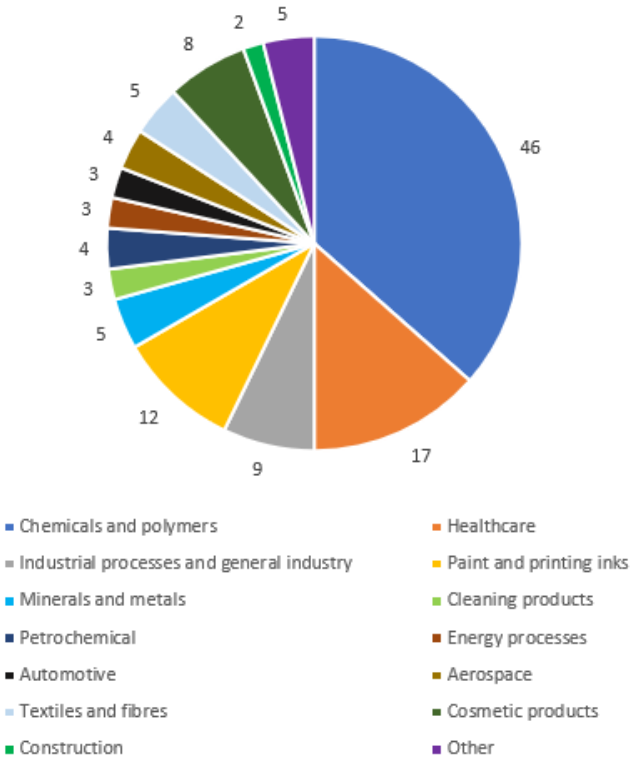
Figure 1 : Number of stakeholders per type of organisation



[3] Participants who during the registration indicated their willingness to take part in the active discussion in the break-out sessions.

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.

Figure 2 : Number of stakeholders per type of industry sector[4]



2.4. Summary of the introductory session

Kristin Schreiber (Director at DG GROW, European Commission) provided a welcome speech that introduced the context of the REACH reform and the workshop's objectives. She explained that the extension of GRA announced in the Chemicals Strategy for Sustainability (CSS) aims to speed up the substitution of the most harmful chemicals through amendments of the REACH Regulation and other legislation.

She offered three main reasons for why the substitution process is slower than expected:

- Complex authorisation or restrictions processes – the subject of two workshops on 9 and 12 November 2021;
- Inappropriate criteria and tools to assess authorisations and restrictions – the subject of a workshop on the essential use workshop on 3 March; and
- Detail of required analysis.

Currently, competent authorities must demonstrate that a substance poses an unacceptable risk before it can be restricted and this requires a thorough scientific basis. However, authorities face a significant challenge due to the lack of available data. In particular, data on uses, which was the subject of the workshop, is hardly accessible to the authorities and

[4] "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.

often incomplete. Moreover, the restriction process of individual substances is lengthy and bears the risk of regrettable substitution[5].

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 was the subject of 21 March workshop and part of a study which assesses different options for addressing the aforementioned issues.

Following the welcome address, **Giuseppe Casella (Head of REACH Unit, DG GROW, European Commission)** presented the background of the workshop and the GRA concept. The GRA concept will be implemented in REACH by empowering the European Commission to introduce restrictions through implementing regulations – i.e. the European Commission will be allowed, but not obliged, to propose such restrictions for all substances and uses in range. Implementation will most likely take place in a stepwise manner.

In order to give a correct assessment of likely impacts, it is necessary to define more realistic scenarios. Indeed, the empowerment of the European Commission alone would not have any direct impacts. Furthermore, 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. 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.

Mr Casella underlined the challenges of identifying the concerned substances, especially for hazard classes where currently there is 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 a considerable task, it will be necessary to focus on the most important substances and uses – such as those which are likely to be 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 cross-checked with stakeholders, which is the purpose of the workshop and the contributions sought from workshop participants.

Following the opening speeches provided by the European Commission, **Becca Johansen (Ricardo)** presented the results of their Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability[6] (CSS) commissioned by the **European Chemicals Industry Council (CEFIC)**. This study sought to assess the economic impacts on the EU chemicals industry of the inclusion of additional hazard classes in the CLP Regulation and the extension of GRA to additional hazard classes and professional uses under REACH, as announced in the CSS. The methodology and scope of the impact assessment were presented, including the steps for defining the baseline scenario, reviewing the commitments outlined in the CSS, mapping the business and economic impacts and assessment of the most significant impacts. On top of the baseline scenario, the study considered three scenarios: the addition of hazard classes to CLP and the extension of the GRA (scenario 1); a five-year implementation timeline of the GRA and CLP changes (scenario 2); and the quick implementation of policy changes of scenario 2. In particular, Scenario 3 assessed impacts on businesses which cannot bring substitutes to the market in a timely manner in the case of quick implementation of change. Two timelines were used for the analysis of impacts: a five-year implementation and a phased approach to implementation. The economic impacts of the reform were presented in terms of the portfolios of companies expected to be affected by the introduction of GRA, and of the sales volumes of certain sectors. The presentation by Ricardo is provided in **Annex 3.**

[5] A situation in which a substance can be replaced by a substance that might not be significantly less hazardous.

[6] https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf

The plenary morning session was closed by **Olaf Wirth** of the **VVA Consortium**. He presented the methodology and the preliminary results of the use mapping, highlighting 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 extension of GRA, which will include considerations of different scenarios of how the GRA could be implemented. The starting point of the research constituted an establishment of a master list of substances with intrinsic properties that might be considered under GRA. These substances were grouped by hazard class and divided in two baskets:

- **Basket 1 – Substances with confirmed hazard(s):** For hazard classes included in the classification, labelling and packaging (CLP) regulation, the inclusion of substances in basket 1 is based on either their harmonised classification (inclusion in Annex VI to CLP) or the reported self-classification in the registration dossier[7]. For other hazard classes, these are based on identification as Substances of Very High Concern (SVHCs) (inclusion in the Candidate List), identification under the Biocidal Products Regulation (BPR) or agreed in the 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. For this basket, there is an estimate on the number of substances for which the hazards are likely to be confirmed (based on past experience[8]).

The master list of substances contains more than 4,770 substances; 3,510 from Basket 1 and 1,261 from Basket 2. However, some substances are listed more than once because they are assigned to several hazard classes or have different classification bases, the exclusion of such duplications reduces the list of individual substances further. The list of substances and respective hazardous properties were retrieved by ECHA from the REACH registration dossiers.

Basket 1 included mainly STOT RE/SE and respiratory sensitisers, while Basket 2 included mainly ED, PBT/vPvB and PMT substances. Basket 1 contained nearly 55% substances of the hazard classes STOT RE/SE and another 11.6 % of Resp. Sens. and 32 % CMR 1A/1B. Basket 1 contained far less substances of the hazard classes PBT/vPvB, PMT and the two ED categories (all below 1 %).

In contrast to basket 1, basket 2 reflected the opposite situation. Only a comparatively small number of substances can be assigned to the STOT SE/RE (1.8 %/5.6 %) and Resp. Sens. (5.6 %) hazard classes. On the other hand, there are considerably more substances from the PBT/vPvB (24.7 %), ED (34 %) and PMT (28.2 %) classes for which further data are required for a final classification of the properties (possibly also non-standard data according to the current REACH Annexes, so that limited data availability can also be assumed here).

Regarding uses, the importance of good definitions of consumer and professional uses was highlighted for the implementation of GRA. When taking the data from the registration dossiers, the study team based itself on the uses as assigned by the registrants. The study

[7] 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.

[8] Note: There can be overlaps between Basket 1 and 2 for cases where the evidence on one property is already sufficient while for another property, additional data are needed.

team indicated that the future extension of GRA is likely to be applied to professional uses when these are similar to consumer uses, regarding the assumed risks.

Finally, it was clarified that the objective of the different break-out groups was to scrutinise the findings on uses based on data retrieved from the registration dossiers and presented in the use maps. It was highlighted that data from registration dossiers have some limitations, especially the lack of most recent updates. The stakeholders were invited to validate the findings and to fill the existing data gaps, to the extent possible, in the break-out group discussions. The presentation by the VVA Consortium is provided in **Annex 4**.

At the end of the opening plenary session, stakeholders were invited to provide questions and comments on the content of the morning plenary session. 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 three groupings from ECHA. However, it included a broader number of substances than the ECHA list of substances. It was clarified that the use maps presented during the workshop by VVA Consortium was based on the harmonised classifications and/or the classification from registration dossiers for Basket 1. Equally, in case of Basket 2, the registration dossiers constituted a starting point for identification of substances. 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 based on harmonised classification and Annex VI of the CLP Regulation. The endocrine disruptors list was developed based on recommendations provided by ECHA. The VVA Consortium highlighted that 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 an export ban on substances, the interconnection between GRA and the essential use concept, the importance of downstream users and the GRA application. The discussion also focused 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 role for the assessment of expected impacts of the future regulatory change. Some factors, such as availability of new product alternatives and 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 be also under scrutiny. Due to the vast array of substances and uses, it was necessary to prioritise assessment of 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 those taking place outside of industrial settings. It was clear that there are borderline cases to industrial uses which might need to be clarified. The European Commission said that one scenario is to focus restrictions on only certain professional uses where the exposure risk is high and to control exposure 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 would not necessarily be linked to the number of substances restricted. In fact, each restriction could have a wide range of impacts depending on the substance’s importance and its potential 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 to what degree such derogations would be necessary or eventually granted.

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; and
- The level of technical functionalities.

The groups also aimed to assess 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 from one another, as the discussions often took different paths aligned with the needs of active participants.

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 prepolymers for mixtures, additives). Additionally, a downstream sector assocciation of plastic converters was present, as well as some representatives from the competent authorities of Member States.

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 and epoxy resins) are plotted against frequently occurring TFs to determine the 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 carry out 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 that uses for PC 32 are more precisely identifiable than the ones 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 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 again the extent to which the monomers are included in the lists through which polymers are registered according to Article 6(3). In that respect, it was precised that monomers have often several hazardous properties and are used under industrial conditions,

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 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 since the vulcanisation process also leads to incorporation of ingoing substances and the end of their existence – 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 and frequency of use) 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 should not be adressed 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.

Participans also asked about the reasons for not including vPvM substances in the assessment in the same way as 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 in 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 overreaching remark, participants suggested that an assessment of the frequency a substances has been assigned to certain uses could help refine 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 emphasised 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 pilot cases to gather the level of granular data required for the impact assessment.

Additional relevant data sources and stakeholders

- *Data sources*
  - ETRMA Statistics Report: https://www.etrma.org/wp-content/uploads/2021/12/20211215-Statistics-booklet-2021VF.pdf
  - Mapping exercise – Plastic additives initiative: https://echa.europa.eu/de/mapping-exercise-plastic-additives-initiative
  - PlasticsEurope Plastics - the Facts 2021: https://plasticseurope.org/knowledge-hub/plastics-the-facts-2021
- *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*

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 regards to the latter, participants highlighted that it is a very difficult exercise that could be nearly impossible 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 readily available to 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 might constitute regrettable substitution.

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

The participants emphasised 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 nearly all kinds of articles. Participants enquired whether the European 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', 'industrial use' and 'consumer use'.

Additional relevant data sources and stakeholders

The participants suggested crosschecking the use maps available on the 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 making 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 regards to further development of the impact assessment

The participants considered that, in order to carry out a meaningful impact assessment, additional elements must 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 could have a safer toxicological profile but a lower technical performance, requiring a higher frequency of application, which could 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.

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. Additionally, some representatives of nanotechnology, tobacco and the veterinary industries were also present, along with several representatives from the competent authorities of Member States.

General issues discussed

The **definition of what is a 'laboratory chemical'** as a substance or mixture used in a laboratory was noted as requiring further clarification to avoid misunderstandings. However, all participants agreed that an analysis of manufactured substances to control their quality (purity, composition etc Should not lead to them being 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 highlighed that it is unclear how to

interpret the term “controlled conditions” in the SR&D definition (Art 3(23) REACH), thus 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 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 emphasised 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 to many different products.

Several 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 the case 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 whether uses were relevant and current or whether substances had been registered for PC21 to ensure a full market coverage and no updates had taken place.

It was also stated that the granularity of information on the uses is not sufficient for the impact assessment, specifically with regards to the lack of information for making decisions 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 those used in very small amounts. The high number of substances registered in PC21 was therefore not surprising to the stakeholders.

In addition, the participants of the break-out group emphasised that a large number of laboratory chemicals were not registered under REACH but could be subject to restrictions. Substances which among others are 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 considered 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, consulting the registrants was suggested 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 making use of existing data sources already in the hands of ECHA, such as the SCIP database and 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 to be mostly 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 PC 21.

Additional relevant data sources and stakeholders

- It was noted 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 said they had 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 grouping of chemicals for restrictions under art. 68(1). Both would increase uncertainties and burden on industries.

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. Additionally, several representatives of the broader category of chemical and packaging industries along representatives from NGOs and the competent authorities of Member States were present.

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 PC18. 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 PC18;

- Plant protection products, paints and dry cleaning[9] 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 leather sofas for example.

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.

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 regards 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 merely paper, textiles and leather, for example.

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 the proportion of their substance portfolio that could be affected by GRA concluded that it would be a very significant.

[9] Dry cleaning uses solvents and solvents should not be used on leather.

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%, while for others the proportion could be 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 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 highlighted that some hazardous monomers may become harmless when processed into a polymer.

- ***Consumer use versus professional use***

There was a wide agreement that the definition of professional use, such as the difference between industrial and consumer use, needs to be clarified. It was noted that one of the additional qualifiers for determining the use category could be the availability of training.

It was also pointed out that consumers can buy haircare products aimed at professional uses (hairdressers), while construction workers can be exposed to substances both as industrial and professional use.

Additionally, participants 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
- *Stakholders*
    - Industry representatives
    - EuPIA: the European Printing Ink Association

3.5. Group 5 - PC 24: Lubricants, greases, release products, PC 25: Metal working fluids, PC 31: Polishes and wax blends, PC 15: Non-metal-surface treatment products, PC 16: Heat transfer fluids, PC 17: Hydraulic fluids, PC 13: Fuels, PC 14: Metal surface treatment products, PC 38: Welding and soldering products, flux products

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 to representatives from the competent authorities of Member States.

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 greatly 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 focused mostly on 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. 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 for the readability of the use maps. Several stakeholders suggested 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 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. However, 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 an exercise if the lists of substances were 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 emphasised that

the industry should identify the substances of concern on a regular basis. It was further highlighted 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 5 to 8 years).

The given 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 European 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, participants pointed out that it would be important to check the extent to which the reported data refer to a unique number of substances concerned since some substances can be present in multiple hazard classes. In turn, such overlaps could create a considerable overestimation.

Second, some stakeholders noted that the allocation to professional and consumer uses in registration dossiers has evolved over time. Given the considerable methodological improvements over the years, one needs to be careful when comparing this data. 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 mirror the real working situation. In fact, it was pointed out that some substances reported as consumer uses are in practice unlikely to be used by consumers. Several participants suggested that technical function could be helpful in defining the dividing lines between consumer and professional uses.

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

Not applicable as this PCs do not include uses in articles. Additional relevant data sources and stakholders

- *Data sources*
    - Individual use mapping conducted by representatives of lubricants, metal working fluids and fuels sectors;
    - ECHA library: Cartes des utilisations - ECHA (europa.eu).

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 of companies and sector associations comprised mostly representatives of cleaning and detergents, and the fragrance and cosmetics industries. Additionally, some representatives of the broader category of chemical and pharmaceutical industries were also present, along with representatives from competent authorities Member States.

Missing uses, technical functions or products

Apart from the obvious errors (e.g. technical function = “service life of articles”), the participants did not feel themselves to be qualified to declare some TFs irrelevant, mainly due to a significant part of the uses being unknown to them. Another reason is that the exercise seems difficult to carry out without knowing the substances concerned. Similarly, participants did not wish to express a view on 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 maps and the impact assessment exercice. The most common argument was that the impact may not be proportional to the number of substances restricted. In fact, restriction on only one substance could have a huge impact, whereas restrictions on a group of many substances could have only a small one.

In general, an extension of the scope of GRA was uncleaer to stakholders for multiple reasons: choosing a hazard rather than a risk approach; the extension could be understood as a systematic ban; investing in trainings for the protection of professionals should be prefered to the extension of GRA to professional uses, etc. As a result, the methodological challenges of the use map discussed during the workshop 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 jeopardise some biocidal product authorisations.

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

Finally, several areas requiring clarification were pointed out such as the identification of EDs (or PMTs) in Basket 2 and the definition of professional use. It was also noted that the difference between some professional uses should be made clear rather than considering all professional uses alike.

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: registrants might not be informed about all uses; downstream users may have not upstreamed actual uses; and 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. In other words, 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 (independent 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***

Professional uses should not all 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.

Additional relevant data sources and stakholders

- *Data sources*
    - Poison Centres Notifications would allow relevant data on actual uses compared to the expected ones to be obtained. Nonetheless, legal obstacles could prevent access to such data and an aggregated database is not expected before 2025.
    - SCIP database could provide some indications, although it is expected that the bulk of the data will be on substances outside PC35, PC8 and PC4.

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 comprised representatives of companies and sector associations in the pharmaceutical and cosmetics sectors. Additionally, some representatives of toxicology and testing associations, along with NGOs and the competent authorities of Member States, were also present.

Due to time constraints during this break-out group, most of the discussion focused on the issues of general data, selected methodology and cosmetics products.

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

The participants highlighted a general issue regarding the quality of registration data as a basis for assessing the impacts of the extension of GRA: some registrants may have ticked many uses and TF boxes as a precautionary measure to maintain access to potential markets. The registration data can also be outdated to some extent, 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 to be not relevant to the PCs of the group, and several participants expressed the need for further work to narrow down lists. While certain TFs could be missing, the general feedback was that there could be many non-relevant TFs (e.g. paints and inks, flame retardants and cosmetics). On the other hand, some participants felt it difficult to discard a given TF given the very high number of chemicals and associated functions in these PCs, of which some are unknown to participants. Furthermore, one substance has general uses in several PCs (e.g. a fragrance used in cosmetics and detergents). Generally, as in previous break-out groups, participants found it 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 would allow for a meaningful and reliable delineation of professional and consumer uses. 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) overlap 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 (e.g. shampoo and 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 to be 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 seven CMRs that the industry itself has identified. A reference was made to an ongoing impact assessment commissioned by fragrances association to Ricardo. The study has not yet been finalised[10].

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 to be 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. Using TF as a proxy was discussed in more detail as it was questioned whether substitution costs can be approached meaningfully using the

[10] The finalisation of the study is expect in mid-2022.

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 being carried out on use maps in order to check and narrow down the lists to that which is significant for the impact assessment, by using available sectoral information (such as the CosmIng 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; and

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

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

Furthermore, participants suggested disaggregating EDs from PBT/vPvBs under the impact assessment. In the presented use maps EDs and PBT/vPvBs were grouped together. For several stakeholders this grouping did not 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 other chemicals. Despite not being under the scope of GRA, alternatives to chemicals discarded because of the GRA can still pose hazards. This should be assessed as potentially reducing the environmental and health benefits of implementing the GRA, according to one participant.

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 cosmetics legislation for their human health hazards), to generate additional data in order to verify whether they would be covered 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.

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 very often use 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. Additionally,

some representatives of telecom, textile, and recycling industries, along with NGOs and competent authorities of the Member States, were present

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 the substances 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.The identification and assessment of those substances is not very advanced and thus should be prioritised. 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 emphasised specific considerations for their sectors:

- The CMR hazard class is less relevant in the discussion of GRA extension given that they are already covered. Data on metals is readily available on releases to consumers in the use life which could provide key 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 a major area of consideration. While 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, which the methodology should take into account.

Several participants also pointed out that broader discussion on the GRA introduction should in their view be had before the next workshop in June and be related to 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 European 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 European 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, since using PCs as the basis for the analysis of complex articles breaks the REACH logic of articles and mixtures. The contractor explained that the 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 of “once an article always an article” (recently confirmed in a court judgment) needs to be maintained in the extension of the GRA approach. Defining the presence of hazardous substances as relating to homogenous materials, components or whole articles should be considered. 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, especially in regard to complex articles, since 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 that helps 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 greatly differ 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 constructed 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 them.

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, which is very limited. Collection of information in the value chain requires considerable resources and long timeframes.
- 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 understimated.

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 carried out analysis that could support the use mapping. For example, Denmark has published over 100 assessments on consumer products which collected much information on hazardous substances in consumer products.

4. CONCLUDING REMARKS

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 that allows 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 for presentation to the European Parliament and the European Council, as well as assessing the likely impacts. 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, prioritising 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.

Furthermore, the European Commission highlighted that the starting point of the GRA will be to focus on particularly hazardous substances and uses with exposures that are difficult to control. The discussion on safe use will be part of the following workshop in June 2022. Concerning uses already assessed as safe that would be targeted by an extension of the GRA, the continuation of the use will need to be assessed, while the use of derogations could be considered. 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. Additionally, 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 2022.

The European Commission also emphasised that animal testing is an important element to consider. However, assessments are required on 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 noted 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 was discussed in the CARACAL-44 meeting on 23 March 2022.

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 public consultation, a targeted survey for the industry and Member States was lancuhed 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 in June 2022.

At the CARACAL-44 meeting on the 23 March, a European Commission paper on the implementation of the GRA was discussed. Furthermore, a joint meeting of CARACAL, the Advisory Committee on safety and health at work and its Working Party on Chemicals, took place on 5 April and focused on work protection and chemicals.

The impact assessment itself will be carried out following the Better Regulation Guidelines. Based on analysis of 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).

5. ANNEXES

5.1. ANNEX 1: Agenda - workshop 21 March 2022

FINAL AGENDA **Workshop on the extension of the generic approach to risk management (GRA) under the REACH Regulation** **21 March 2022 – online**	
8:30-9:00	**Online connection** of participants
9:00-9:15	**Introduction** • Welcome, presentation of the study in the context of the REACH revision and workshop's objectives (*Kristin Schreiber, Director at DG GROW, European Commission*) – 10' • Practicalities of the workshop (*Lucas Porsch, VVA*) – 5'
9:15-10:35	**Presentation of the GRA approach and study** • European Commission approach to the extension of GRA and the link to the essential use and derogations (*Giuseppe Casella, Head of REACH Unit, DG GROW, European Commission*) – 15' • Presentation of CEFIC study: methodology and results (*Becca Johansen, Ricardo*) – 15' • Presentation of the study: methodology, use maps and how they are used to assess impacts (*Olaf Wirth, Oekopol*) – 20' • Discussion and Q&A – 30' Moderator: *Otto Linher, Senior Expert, REACH Unit, DG GROW, European Commission*
10:35-11:00	Coffee break
11:00-12:30	*Participants will be allocated to eight online break-out groups, organised on the basis of substance or product categories (see workshop background paper with relevant details). The eight groups will remain the same in the morning and in the afternoon. Each group will discuss the key assumptions and results of the use maps presented.* *The morning session will focus on **identifying the key gaps** in the use maps, the methodology and data source. For each of the online groups, there will be a moderator and a rapporteur from the European Commission or the VVA Consortium.* **Break-out groups – morning session**: • 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 5 - PC 24: Lubricants, greases, release products, PC 25: Metal working fluids, PC 31: Polishes and wax blends, PC 15: Non-metal-surface treatment products, PC 16: Heat transfer fluids, PC 17: Hydraulic fluids, PC 13: Fuels, PC 14: Metal surface treatment products, PC 38: Welding and soldering products, flux products; • 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 *PC = product category assigned in registration dossiers, according to ECHA guidance*
12:30-14:00	Lunch break
14:00 – 15:15	*In the afternoon session, each group will focus on the identified gaps and further develop **potential data sources or methods to fill the gaps and complete the use maps**. For each of the online groups, there will be a moderator and a rapporteur from the European Commission or the VVA Consortium.* **Break-out groups – afternoon session:** • 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 5 - PC 24: Lubricants, greases, release products, PC 25: Metal working fluids, PC 31: Polishes and wax blends, PC 15: Non-metal-surface treatment products, PC 16: Heat transfer fluids, PC 17: Hydraulic fluids, PC 13: Fuels, PC 14: Metal surface treatment products, PC 38: Welding and soldering products, flux products; • 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 *PC = product category assigned in registration dossiers, according to ECHA guidance*
15:15-15:45	Coffee break

15:45-17:30	**Presentation of results and discussions**: • Presentation of results from break-out groups (*rapporteurs from VVA Consortium*, 8-10 min per group) – 80' • Discussion and Q&A – 25' Moderator: *Otto Linher, Senior Expert, REACH Unit at DG GROW, European Commission*
17:30-18:00	**Next steps of the study and IA; concluding remarks** *Otto Linher, Senior Expert, REACH Unit at DG GROW, European Commission*

5.2. ANNEX 2: Workshop background paper

(in separate document)

5.3. ANNEX 3: Presentation of the CEFIC study

(in separate document)

5.4. ANNEX 4: Presentation of the VVA Consortium

(in separate document)