Workshop on the extension of the generic approach to risk management under the REACH Regulation

21 March 2022

Valdani Vicari & Associati
ECONOMICS & POLICY

Agenda

- Introduction
- Presentation of the GRA and study
- Break-out groups (morning and afternoon sessions)
- Presentation of results and discussions
- Next steps of the study and IA; concluding remarks

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Opening plenary session (morning)

Introduction

By:

Kristin Schreiber, Director at DG GROW – European Commission

&

Lucas Porsch, Associate Director – VVA

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Welcome, presentation of the study in the context of the REACH revision and workshop's objectives *(European Commission)*

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Practicalities of the workshop (timeline)

- After this introduction to the workshop, the **GRA approach and the use mapping will be presented**, followed by a **discussion and Q&A**
- After the **first coffee break**, the ***"active"*** participants to the workshop will be asked to connect to their respective **break-out group**, using the link sent to them by email
- The morning session of the break-out group will last for 1h30, and after a lunch pause, the afternoon session of the break-out group will resume at 14:00, for 1h15
- After the **first coffee break**, the ***"passive"*** participants will be able to leave the plenary session, and they should connect to the afternoon plenary session at 15:45
- In the **afternoon plenary session**, the **results** of the break-out groups discussions will be presented to all participants, followed by **Q&A**
- Finally, the **next steps of the study and the IA** will be presented

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Practicalities of the workshop (general information & house-keeping rules)

- The **link** used in the **morning plenary session** should be used to connect to the **afternoon plenary session**
- The **link for the break-out group session** will also stay the same for both the morning and the afternoon session
- Please try to **connect to the sessions at least 5 minutes** before its start, to ensure smooth organization
- Please refer to the **workshop background document** for information on the purpose and scope of the workshop, and of the break-out groups
- Please refer to the **agenda** for information about the precise timeline of each sessions
- If you have **any questions/ issues** during the workshop, please contact: reach_workshop@vva.it

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Presentation of the GRA approach and study

Moderator: Otto Linher, Senior Expert, REACH Unit, DG GROW - European Commission

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Commission approach to the extension of GRA and the link to the essential use and derogations

By Giuseppe Casella, Head of REACH Unit, DG GROW – European Commission

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Presentation of CEFIC study methodology and results

By Becca Johansen, Ricardo for CEFIC

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Presentation of the study: methodology, use maps and how they are used to assess impacts

By Olaf Wirth – Oekopol (part of VVA's Consortium)

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Implementation of the GRA

- **Scope of the Study: Assess Impacts that might originate from the extension of the current GRA approach implemented in REACH Article 68 (2)**
- Article 68(2) **empowers** the EU-Commission to **propose a restriction based on generic exposure considerations** if a substance has **certain hazards**
- **Hazardous properties** and **generic exposure considerations** are sufficient for the EU-Commission to propose and substantiate **new restrictions for consumers**
- Past uses of Article 68(2) in REACH ("old GRA")
  - CMR substances (cat. 1A or 1B), on their own or in mixtures, for supply to the general public via an extension of entries 28-30 of Annex XVII of REACH
  - substances in articles used by consumers:
    - restriction of certain CMR substances in textiles, entry 72 and
    - certain PAH compounds in rubber and plastic, entry 50.
- Similar generic restriction clauses in product specific regulation with relevance for consumers e.g., the Toy Safety Directive or the Cosmetic Products Regulation

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Implementation of the GRA

- Aims of the study:
  - Assessment on **potential impacts** of extended GRA on EU Level – cost and benefits
  - This will include the consideration of **different** (more or less likely) **options on how the GRA** could be implemented
- What is **not** in the scope of the study:
  - **Specification** of the **later specific restrictions** within the framework of the GRA
  - ⇒ **not all areas assessed**, will later necessarily be **addressed by a restriction** under the GRA
  - ⇒ But it **does also not mean** certain **areas are not addressed** by restrictions to establish the political ambition to increase protection towards the most hazardous substances, e.g.
    - ⇒ Restrictions via current Article 68 (1)
    - ⇒ Continuation of the current authorization process
    - ⇒ Recast of product specific legislation (e.g. toy directive, cosmetics regulation, legislation on food contact materials etc.)
- The further **design** and **subsequent use of GRA** is the responsibility of the EU-Commission as the legislative body

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Implementation of the GRA

- The project as contracted by the EU-Commission covers 3 tasks relevant for this workshop
  - Task 2: Mapping uses of the substances that will be subject to the generic approach to risk management;
  - Task 3: Assess the uses that would fall under the GRA and quantify the impacts resulting from the extension of the generic approach to risk management;
  - Task 4: Assess the impacts of reforming the REACH authorisation and restriction processes.
- **Main focus of the workshop is on Task 2**
- Task 3 and 4 are more for the contextual background of the later impact assessment of different options on the GRA extension (task 3) and options on the future design of the authorisation and restriction processes (task 4) – to be discussed in a **second workshop first half of June 2022**

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Implementation of the GRA

- Basis for the use mapping under Task 2 was a master list of substances (MLoS) with intrinsic properties that might be considered under an extended GRA
- MLoS was generated by ECHA was divided by hazard classes and two so called baskets
- **Basket 1 – 3,510 Substances** with **confirmed hazard(s):**
  - **hazard classes included in the CLP- Regulation**, 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** .
  - For **other hazard classes**, these are based on **identification as Substances of Very High Concern (SVHCs),** identification under the **Biocidal Products Regulation (BPR)** or **agreed in the ED/PBT Expert Groups**.
- **Basket 2 –1,261 Substances where the hazard(s) are under consideration:** substances with on-going data generation or assessments;

  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).

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Potential extension

Implementation of the GRA

	Current Scope of GRA (Art. 68 (2))	Envisaged scope of GRA in CSS

Uses covered	• Consumer uses
	  ○ Substances
	  ○ Mixtures
	  ○ Articles
		• Consumer uses
		  ○ Substances
		  ○ Mixtures
		  ○ Articles
		• Professional uses
		  ○ Substances
		  ○ Mixtures
		  ○ Articles

Hazard classes covered	• CMR cat. 1A and 1B	• CMR cat. 1A and 1B • ED (HH and Env) • PBT/vPvB • STOT (SE and RE) • Resp. Sens. • Substances affecting the immune or neurological systems

Also **included in study** use mapping but currently **not mentioned in CSS**: **PMT**

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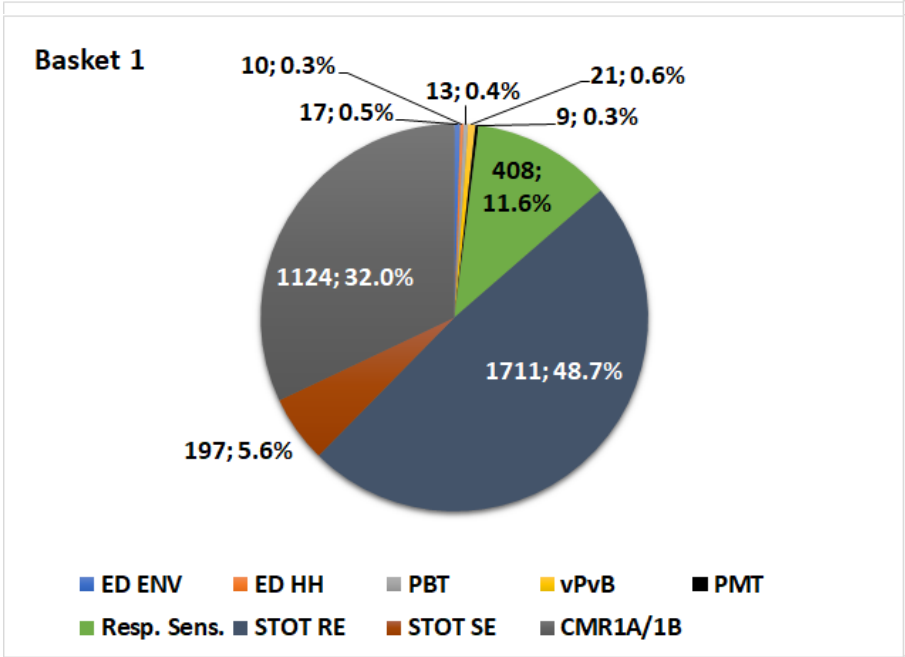
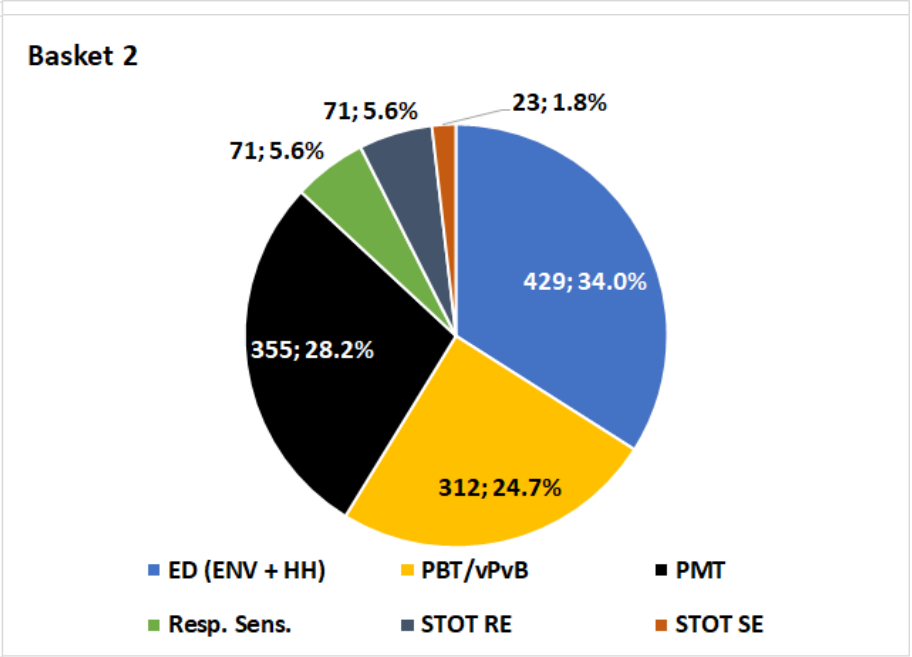
Implementation of the GRA





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Implementation of the GRA

- Step 0: automatic extraction of registration datasets for substances with (expected) hazardous properties falling under GRA from REACH IT (IUCLID section 3.5) – data reflect content and quality of registration dossiers
- Step 1: assessment of which substances per hazard class are assigned to which product categories (PC)
  - First proxy about the extent to which market areas could be affected by restrictions of substances in MLoS
- Step 2: Assessment of registered consumer uses and professional uses within each product category
  - Further specification of potential relevance of future GRA
- Step 3: assessment of technical functions (TF) of substances relevant for consumer and for professional uses and identification of further specified products indicated to be relevant for these substances (mixtures and articles) from registration data (i.e. free text descriptions)
- Findings were presented in aggregated way prior to workshop to participants of break out groups

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Implementation of the GRA

- In the initial use map the assignments of uses by consumers and professional were taken as assigned by registrants
- For deriving options in the IA following preliminary definitions are applied:
  - Use by consumers is any use of a substance on its own, in a mixture or in an article (service life) by a consumer or a private citizen (not taking place as part of a professional or work-related activity).
  - Use by professional is any use of a substance on its own, in a mixture or in an article by a professional that takes place as part of a work-related activity outside an industrial site*
- The GRA is likely to be applied to uses by professionals, when these are similar to uses by consumers regarding the assumed risks. The IA will also include other professional uses where this is not the case

*This definition follows the logic to distinguish uses at industrial sites and uses by professional workers. See ECHA (2015) “Guidance on Information Requirements and Chemical Safety Assessment - Use description (Chapter R.12) https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197?t=1449153827710

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Implementation of the GRA

- Aims for today's discussion:
  - Scrutinise findings from registration dossiers with sector experts and further extension of use maps
    - Elimination of false assumptions on TF or products (articles and mixtures)
    - Refinement of product areas (in particular service life for articles) where certain TF are relevant
      - Example article: flame retardants (TF) are not generally relevant for plastic products but are common in certain polymers (e.g. ABS) within specific articles (e.g. WEEE or even more specific e.g. televisions, computers or parts thereof etc.)
      - Example mixture: cross linker (TF) are not relevant for adhesives but for the use in epoxy resin based 2K adhesives
    - Mapping of TF relevant for complex articles: Identification of areas that could affect the function of complex articles (and thereby cause significant impacts in deeper supply chains)
      - Example: Flame retardants in cables of planes are absolutely relevant due to safety reasons

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Discussion and Q&A

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Introduction to the break-out groups (1)

❖ **Aims of the break-out groups:**

- To **critically review the information extracted from the registration data and the use maps** prepared based on that date and validate them with stakeholders.
- To **confirm, refute or refine the data analysis** of the initial use maps and clarify if the wide assumptions of the use map reflect the market situation properly.
- To **verify a basic level of concern**: the following question will be asked in each group "*is the assessment of concern regarding the hazard class correctly depicted*?". The feedback from the participants will serve to identify which main impacts are expected in case of a GRA restriction and to determine the magnitude of these impacts.

❖ **Focus of the discussions:**

- On the **basic technical assumptions** that form the basis for the actual assessment of impacts, which is planned later in the project.
- It is **not assumed that all questions** can be conclusively addressed in the workshop.
- Therefore, the workshop is also intended as an **opportunity to identify stakeholders** with whom the discussion can be continued to gather further information for refining the use maps.

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Introduction to the break-out groups (2)

❖ **Logistics of the break-out groups:** To enable feedback from participants on the results of the use mapping, the following three steps will be conducted in the group sessions of the workshop:

1. **Step 1 - Presentation on the uses identified in the different product groups:** We shared last week a PPT summarising the key results of the use mapping in the specific product groups. This should have allowed participants to interact also with technical experts in their organisation.

2. **Step 2 – Presentation of current use maps**: Once you join your break-out group after the pause, the moderator and rapporteur will take the group members through the specific results for the product group and will respond to any specific questions on those results. Depending on the number of questions, this step of explaining the results can potentially last the full morning session.

3. **Step 3 – Gaps and further development of use mapping**: Following the clarifications, the members of the group will discuss in which areas the use mapping will need to or can be developed further.

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Break- out groups (morning and afternoon)

Closing plenary session (afternoon)

Presentation of results and discussions

Moderator:
Otto Linher, Senior Expert, REACH Unit at DG GROW – European Commission

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Group 1
PC 32: Polymer preparations and compound

By:
Moderator: Ludovica Rossi, DG GROW

&

Rapporteur: Olaf Wirth, Ökopol

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Results I

Missing uses, technical functions or products

- It was discussed to what degree polymers as such are included in the assessment and it was clarified that no polymers as such are included as they are not registered
- special attention should be given to reactive compounds – can be polymers, monomers or their functional compounds (e.g. cross linker) – no service life relevant, most reactive systems are designed in a way that all substances needed do react
- In a similar way rubber products were discussed as the vulcanization process also leads to incorporation of ingoing substances and the end of their existence as such – it remained open if there are areas of where substances remain in the products
- It was confirmed that also for reactive systems additional additives might be needed for the subsequent use of the material (PUR foam and flame retardants were mentioned) but more precise use areas and functionalities were not brought forward
- Regarding main sectors that are affected participants referred to official sector statistics

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Results II

Methodological challenges of the use map identified

- It was discussed why in comparison to vPvB substances no vPvM were included in the assessment and it was clarified that this was mainly du to the unclear criteria for this area und the high level of uncertainty associated
- A key challenge for participants was the discussion without specific substance lists
- It was proposed to start with an assessment of risk (areas) instead of including all substances in the impact assessment in the same way – it was clarified in this regard that 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, but it is expected to differ in the impacts allocated to the use areas
- It was also asked if there was an assessment of the frequency certain uses have been assigned- it was clarified tat in the initial use map all assignments were included. It was acknowledged that this would be relevant for the impact assessment, as the frequency of selection of a product or a TF might be a proxy for the main uses and niche applications.
- It was discussed if SU or AC would not serve as a better indicator for use maps then PC and it was clarified that this was not the case as these info is often missing

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Results III

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

- when monomers (or other reactive compounds) are registered sometimes the uses of the end-product are reported even if they are not existing in them as such
- It was confirmed that technical functionalities are basically not of bad quality and can be used (of course with some uncertainty in details)
- It was further pointed to a past study performed with ECHA on the mapping of most common used additives, this was indicated a good basis for further refinement
- Challenge to identify uses that are between industrial and professional that might influence impacts
- Companies indicated that they are assessing portfolios to what degree they might be affected by GRA, but there are some constrains in the area ED and PMT in particular as criteria are still under discussion

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Results IV

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

- I was proposed for further refinement of the use areas to draw up a matrix of technical functions and main use areas (articles, mixture types to confirm the relevance of certain functionalities in these use area and to differentiate the broad scope of PC 32 a bit more

Other issues

- It was emphasized to address benefits carefully
  - Not only wider economic benefits for human health or the Env.
  - Benefits for executing REACH processes
  - Also in context with other elements currently discussed in the REACH revision (what might be a benefit in a isolated view can be more complex and burdensome in combination with others

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Group 2
PC 1: Adhesives, sealants

By:
Moderator: David Tyrer – AQ Consultants

&

Rapporteur: Marco Camboni – RPA

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Results I

Limitations of the available data:

- The use maps are just a snapshot in time
- Difficult to interpret the use maps and difficult to validate the information without the master list of substances
- For further discussions with industry, there should be some grouping (e.g. monomers, additives)

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Results I

In order to carry out a meaningful impact assessment, there is the need to define a number of elements:

- **What is professional use / industrial use / consumer use?**
- **What is essential use?**
- **What are the concentration thresholds to be considered? 0.1%? 0.01%?**
- **Where is the cut-off for the consideration of the impacts (costs and benefits)? And how are we going to consider the differences in market values between substances, mixtures and articles? There is the risk to not reflect the actual impacts on downstream sectors, not just economic impacts but also impacts on the technical performance of products (example: coating of a bridge; lower performance, more applications, worst environmental overall performance)**

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Results I

- **Should we use a worst-case scenario? Is it possible to select a representative sample of substances per PC?**
- **Important to consider the overlap between notified professional uses and consumer uses**
- **GRA and essential use concept go hand-in-hand. How to better consider this?**
- **Where and when to consider uses and exposure?**

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Results I – Afternoon session

Any ways forward or around the obstacles?

- **Do not use Technical Functions, they are not a good starting point to make considerations on alternatives**
- **Selecting a sample of substances for further assessment would result in anecdotal evidence, so not good**
- **Is it possible to select a representative sample of mixtures and articles than? Response: high complexity (e.g. mixtures in mixtures), difficult to find information on concentration levels**
- **Use the use maps available on ECHA website to at least validate some of the information**

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Results I – Afternoon session

- **Make use of the information for the Ricardo assessment for Cefic**
- **Consider impact on innovation: loss of valuable chemistry ; new substances are less studied (regrettable substitution)**

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

By:
Moderator: Christian Krassnig – DG GROW

&

Rapporteur: Antonia Reihlen – Ökopol

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Results 0

General issues at sector/PC level

- **Definition of „laboratory chemical“ is unclear**
  - Understanding in the group: a substance that is subject to quality control in a lab is not a lab chemical
  - Should be covered as part of the manufacturing process but not as PC21

- **Limitation of SR&D exemptions**
  - 1 t/year
  - uncertainty about “controlled conditions” (← guidance)

- **Laboratory context in industrial installations is considered an industrial (laboratory) use**

- **Some Stakeholders conducted internal review with different methodology → willing to share information if CBI is ensured and no competition laws are breached etc.**

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Results I

Missing uses, technical functions or products

- **Uses in education (schools) as well as in toys are possible**

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Results II

Methodological challenges of the use map identified

- **Registrants registered all possible uses to ensure their markets are covered but did not revise up to now**
  - Uses are plausible but nevertheless obsolete?
  - The granularity of information is not sufficient for impact assessment, not obvious for what purposes a lab chemical is used (e.g. medical or not) → link to essential uses

- **Understanding of uses detached from specific substances is challenging**
  - "Cleaning up" the use map without going back to the registrants, could eliminate relevant uses
  - Some consumer uses are not plausible (e.g. plating agent)

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Results III

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

- **Substances used (as such or in mixtures) for laboratory purposes which are not registered are not included but might be subject to restrictions**
  - Might be covered by restrictions addressing hazards rather than individual substances
  - Many substances are used in the lab context, which are imported in amounts < 1t/a → not covered by the IA
  - From manufacturers → SDS do not have ES / specify if PC 21 is registered (→ no DU notification)
  - Substances ONLY used for laboratory purposes may exist (e.g. highly specialised diagnostics) → very low amounts

- **Possible mitigation measures**
  - Discussions with registrants (substance wise / line by line) – challenging from the resource perspective
  - Use of sector assessments
  - Sweden: registration of (hazardous) chemicals use in laboratories – matching with database for IA possible?
  - Check DU notifications (not too high hopes), are article 7 registrations included? Check the SCIP database

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Results IV

Discussion on articles and other aspects

- **Articles could be covered, e.g. photographic paper but rather the exception than the rule**
  - Laboratory equipment and medical devices are not in the scope of PC21 but may be affected by GRA

- **Laboratory staff is highly trained; impacts of GRA extension to professional uses in the laboratory context as compared to the industrial setting is therefore questionable**
  - Example: exactly the same use in hospital and in the industrial setting; exactly same risks and exposures → professional / industrial
  - Laboratory may handle lower amounts than industrial installations? Emission control with regard to the environment also similar? Waste disposal should also be well managed

- **Assessment of DU impacts difficult, as information on e.g. new classification of substances is not available yet**

- **Extensive impacts on the medical sector are expected → invitation to reach out and discuss with the sector to improve the data**

- **Discussion about the link between this study and the impact assessment, the need to link with the authorisation/restriction reform, concerns that the data basis is insufficient and information input will not be possible to take up**

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Group 4
PC 34: Textile dyes, and impregnating products, PC 23: Leather treatment products

By:
Moderator: Ana Maria Blass Rico – DG GROW

&

Rapporteur: Daniel Vencovsky – RPA

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Results I

Missing uses, technical functions or products

- **Missing uses? On the contrary, an overestimation**
- **Common sense can help eliminate some nonsensical combinations:**
  - **Food and feed not relevant to textile dyes, fuel additives, fertilisers, laboratory chemicals, adhesives in PC18, PPP for leather, paints for leather**
  - **TFs: Heat transfer agent, Intermediate not a professional use, embalming agent, corrosion inhibitor**
  - **Dry cleaning for leather is not relevant since solvents are not suitable for leather, paints not for leather**
  - **Washing and cleaning should be ok for leather products since – use cleaning for leather sofa**
  - **Professional textile dyes not really that relevant, leather also not that relevant**
- **For a positive list, we need to know the substances**

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Results II

Methodological challenges of the use map identified

- We need to revise some categories (products too high level, inks related to pens, toner is used in offices)
- Even where the methodology is correct, need to verify if data are current
- It is difficult to predict the future classification of chemicals, e.g. ED
- For mixtures, it is possible to have a good idea but less so for articles
- Also, imports are a gap (imported articles)

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Results III

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

- More detail needed to assess the impact GRA (paper, textiles, leather, what are the products: flame retardants, ink)
- We have reached the limitations of what we can reach from registration dossiers -> cannot be fixed with these data
- Look at other databases: SCIP (only SVHCs), Poison Centre database, linkage with BREFs with registration dossiers
- We need a check by the industry, we can have more information from the industry, there are also stakeholder not present today

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Results IV

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

- **Hazard classes potentially relevant for substances in your production processes**
  - Difficult to say because definitive lists of relevant hazard classes are not available
  - Some companies have done a check on their substance portfolio and preliminary results suggest a large proportion of substances
  - 1/3 of total chemicals will be assessed in GRA (very broad prediction) but we do not have current data
  - We need a survey to have something meaningful for some it may be 90% for other just 1%
- **Type of product or article**
  - The bottom line is that it is about the presence in articles that can be accessed by consumers but also exposure?
  - But also about exposure, need to consider risk (tanning agent, monomer->polymer)
- **Consumer use versus professional use**
  - Lack of clarity what the data tell us, at which point professional use occurs, e.g. curing leather, fixing a pair of shoes)
  - Lack of clarity on definitions: Hairdressers: consumer vs professional – consumers can buy professional products, construction workers
  - Other qualifiers, e.g. training
  - Consistency: if additional explanations are provided for borderline cases, only useful in the future

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Group 5
PC 24: Lubricants, greases, release products and PC 25: Metal working fluids

By:
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&

Rapporteur: Magdalena Klebba – VVA

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Results I

Missing uses, technical functions or products

- Overestimation of number of substances in different PC(e.g. PC 24). Substances, that are typically used should be further retrieved.
- Uses for a readability purpose could be classified in broader group categories (e.g. based on commonalities).
- Inadequacy of some substances for consumer uses in practice
- Individual use mapping done by lubricants, metal working fluids and fuels sectors (based on ECHA guidance). However, no investigation was undertaken on whether identified uses would fall under GRA.
- Some use maps from individual sectors are published on the ECHA library. Some of these will have updated SPERC background documents based on the format agreed in 2016

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Results II

Methodological challenges of the use map identified

- **The number of substances doesn't provide much information –> what's more important is the tonnage for the different uses and the concentrations in the final products. If below the classification concentration limit, the mixture would not be restricted/**

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Results III

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

- **Extent to which data refer to unique number of substances concerned as some substances can have multiple hazard categories. This can create a considerably overestimation.**
- Split between professional and consumer uses over time in the registration dossiers. The important improvements have been done over the years.

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Results IV

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

- **Hazard classes potentially relevant for substances in your production processes**
  - Industry seems to may efforts to identify the substances of concern on the ongoing basis.
  - It would be helpful for the exercise, if the lists of substances could be shared with sectors. It would also help industry to prepare for substitution, if they could be informed about substances in Basket 2 under investigation**Type of product or article**
  - Long term required for substitution (e.g. PC 24, between 5-8 years.
- **Consumer use versus professional use**
  - The use mapping should be more adequate. Some substances are possible for consumers use, in practice they are not. The consumers and professional uses should be more critically reviewed to mirror the true situation.
  - TF could help in making division between consumer and professional uses.

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Group 6
PC 35: Washing and cleaning products

By:
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Rapporteur: Pierre Boucard – Ineris

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Results I

Missing uses, technical functions or products

- **In general, not possible to state which are not relevant**
  - Wish not to speak for others (SMEs, …)
- **No statement neither on which should be the most relevant**
  - Difficulty to speak without knowing substances
- **No missing important uses or technical function were identified**
  - Not possible to identify any additions because actual substances are not known
  - Hard to speak hypothetically
- **No discussion on specific substances**

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Results II

Methodological challenges of the use map identified

- **Difficult to understand how the data presented can be used for IA**

- 1 substance can have a huge impact
- A group of many could have a small one

- **Specific issue on substances covered by several regulations**
  - *BPR (issues linked to the Review program – authorisation processes of products)*
  - *Cosmetics*
  - *OHS*
  - *Greater attention should be given to uses not covered by other legislations*

- **How EDs (or PMTs…) were identified in Basket 2 should be clarified**

- **All or some professional uses ?**
- Clear definition of professional use is needed

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Results III

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

- **Some uses may be legacies which are not relevant anymore**
  - Potentially obsolete (can we know ?)
- **Conversely, potential gaps**
  - Registrants might not be informed about all uses
  - Downstream users may have not upstreamed actual uses
  - Notifications by downstream users about the uses are not always included in registration dossiers
- **Can we assume a global balance ?**
- **Tonnage bands could be a proxy for the importance of the substance but some important limitations (some important substances can be used in really small amounts)**

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Results IV

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

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

- **Type of product or article**
  - Really difficult to state

- **Consumer use versus professional use**
  - Concerning professional uses, all of them should not be considered the same way (e.g. analytical labs vs hairdessers)

- **Some other data sources may be relevant**
- Poison Centers Notification
  - *Actual uses vs Expected ones*
  - *But potential legal obstacles*
    - *No aggregated database before 2025*

- SCIP database
  - *Some indications*

- Other issues :
  - *How to deal with other aspects (tradeoffs between different goals in the Green Deal) ?*

- **Could the deadline for written comments be extended ?**

Group 7
PC 39: Cosmetics, personal care products

By:
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Rapporteur: Jean-Marc Brignon – Ineris

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Results I

Quality of registration data and overall technical comments

Many uses and TF boxes ticked by precaution

Data might be outdated

IUCLID data

Some (many?) TF and Uses appear indeed not relevant to PC => preliminary work to narrow down

Interpretation of ECHA Guidance on registration, in particular difference P and C uses.

Does raw data allow for meaningful and reliable delineation of P and C uses?

Distinction between P and C not very relevant for cosmetics (same markets and same formulations basically)

Difference between P (pharmacists, doctors) and C (patients) for pharmaceuticals : what impact on assessment ?

Impact assessment / Policy questions

GRA could reduce number of chemical and increase exposure to these chemicals

Even if not under scope of GRA, alternatives to GRA-chemicals can still have hazards

Some specific chemicals might drive the impact (e.g. alcohols…)

Impacts not only correlated to number of chemicals

What is the methodology for impact assessment, what use of the lists of TFs and numbers

Where to find relevant volume information ? (IUCLID questioned)

Impact of GRA on animal testing

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Results 2

Cosmetic

Itself a universe of chemicals within chemicals

Difficult to define boundaries of this PC

Need to work with refined product categories to understand functions and substitution (shampoo, lipstick,…)

One chemical has in general uses in several PCs (e.g. one fragrance used in cosmetics and detergents)

Difficult to discard a given TF given high range of chemicals /functions / products

Fragances

Presence of CMRs and Respiratory sensitizers surprising since they are not allowed, and are not used according to industry association

Air fresheners

Difficult to define,

Pharmaceuticals

Many CMRs = might indicate presence of active pharmaceuticals ingredients (not relevant for REACH)

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Results 3

Proposals for further work on use maps and impact assessment

Desirable to work chemical by chemical, or at least
Work with ECHA and industry on a reduced set of chemicals
Carry out consistency checks with other legislation (Cosmetics Directive)
Use available data to narrow down lists (CosIng for cosmetics)
Use number of occurrence of TFs as a proxy for its importance for further analysis
Important to collect information of uses exposure and volumes

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Group 8
Complex articles

By:
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Rapporteur: Lucas Porsch – VVA

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Results I

Missing uses, technical functions or products

Many discussions revolved around how the information could inform a prioritisation process and which other information could

- **Generally difficult to say which PCs are more relevant than others. Dozens of PCs are relevant for manufacturers. Car industry is all industrial use meaning that even though they are many relevant substances, the industrial use makes is less relevant and if all substances that come in contact with consumers are covered the complexity of the supply chains makes a response difficult.**
- **PC7 is an important category for complex products, on the production side this is very industrial but consumers and professional use in repair and use also needs to be considered.**
- **Other examples should distinguish between empowerment and relevance: Examples for differences in relevancy were:**
  - **CMR is not so relevant for consumers (as already covered) while other hazard classes are. For metals there is good data on releases on consumers in the use life which could provide important information.**
  - **Sewage treatment plants**
  - **Biocides available to the consumers**
  - **Tyre release**
- **EDs are underrepresented in basket 1 of the analysis but this will change soon as their strong presence in the basket 2 already shows. This is important and EDs would probably come early in the prioritisation process.**
- **Consumer articles should be dealt with first due to less options to safeguard them**
- **A broader discussion process on the GRA process is needed and the June workshop might be to later for it.**
- **Differences in private and professional use (e.g. Textile and use of PPE or not) exposure is therefore more important in the private sector**
- **Essential use concept is crucial for the IA**

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Results II

Methodological challenges of the use map identified

- Using ACs instead of PCs would result in better coverage for complex articles. The analysis breaks the REACH logic of articles and mixtures. To avoid misinterpretation that should be avoided although of course there is the challenge of value chains.
- The recently confirmed principle Once an article always an article needs to be maintained also under GRA. On the other hand, only the last article is very often a consumer article. Complex articles production processes are putting other articles together. But this production process is not part of REACH.
- Some uses are designed to avoid release of the chemical others are designed to release. The risks of those very much differ and the methodology should take account of that
- Distinguishing between professional use and industrial use is a challenge. Most complex products Question: What is industrial use in industrial product? Complex articles are mostly produced industrially, but they are used by consumers and repaired by professionals. This needs to be taken into account.
- For metals and inorganics this will be mainly CMR (if still not regulated) and skin sensitisers after close and prolonged contact.
- For CMR substances the information is available in textiles and the key question of protection and risk is how fixed the substances are in the garment
- How will this be translated into an IA with the uncertainties of timetable and coverage still in play? The key use will be a prioritisation tool, but it is important that not too many assumptions and limited data do cause faulty assessments.

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Results III

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

- Medical devices are often very complex products. Data is available only in safety sheet and is very limited. Collection of information in the value chain requires a very long time and a lot of resources.
- Another key challenge is that chemical companies do not know what happens downstream with their products (only for direct customer But no legal requirement is supporting this data collection effort. How can the manufacturer know?
- Mixtures and substances become articles at some time which changes the requirements completely (and only in Europe) – So any change will require a change to the whole infrastructure
- Without the CAS numbers it is not clear how a meaningful analysis for this IA can be done.
- Challenge of data availability in small companies. While large companies might have the resources and the heft with suppliers to ask for data small companies have not (and large companies also report to SCIP)
- SCIP database could be used further used but it requires prioritisation first
- Recommendations needed to organise the data collection in companies better. Practices are differing a lot (including SCIP could be an example). Meeting SCIP requirements is already difficult and will increase further if more substances need to be tracked.
- Denmark has published over a 100 assessments on consumer products collects a lot of information on hazard categories in consumer products

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Results IV

Other points mentioned

- Restricting specific substances in specific articles is already done e.g. in fashion and future restrictions could be done like that
- How will the derogation system work and what will be the costs and timings of the process?
- Dual use concept is an important issue to consider. (From ROHS Directive) if some parts are subject to the Directive and some are not.
- Are we moving towards homogenous materials? Some part of the answer is in which products we look as some are more homogenous but timing will probably not allow a full analysis

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Discussion and Q&A

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Next steps of the study and IA; concluding remarks

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Otto Linher, Senior Expert, REACH Unit at DG GROW – European Commission

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Next steps – impact assessment

- **The team is preparing an impact assessment on the extension of the GRA. Next steps include:**
  - Consultations
    - *Target survey for industry and Member CAs*
      - To further understand impacts of the extension of GRA on sectors and different actors in the supply chains
      - It will include questions on current uses, expected industry responses, economic effects and potential implications on product functionalities.
    - *Interviews with stakeholders*
      - To further explore questionnaire responses (targeted survey and from the wider Public Consultation).
  - Preparing the impact assessment
    - *Baseline (continuation of status quo)*
    - *Impact assessment of the extension of GRA to more hazard classes and to professional uses*
    - *This will be based on the use maps, the results of todays workshop, and the targeted surveys and interviews*
    - *Integration of the "essential use concept"*
  - Workshop on validation of the finding of the impact assessment of the extension of GRA – early June

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Next steps – impact assessment

- **In parallel, the study will also assess the impacts of options for revision of the authorisation and restriction process**
  - *The target surveys and interviews will also explore effects of an agreed number of potential options*

- **Timeline for both assessments:**
  - Consultation with industry
    - *Targeted survey: April*
    - *Interview: April - May*
  - Preparing the impact assessment: April-May
  - Workshop on validation of the impacts assessment: June

  - Your input is crucial to ensure we accurately identify and evaluate effects!

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Thank you for your attention!

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