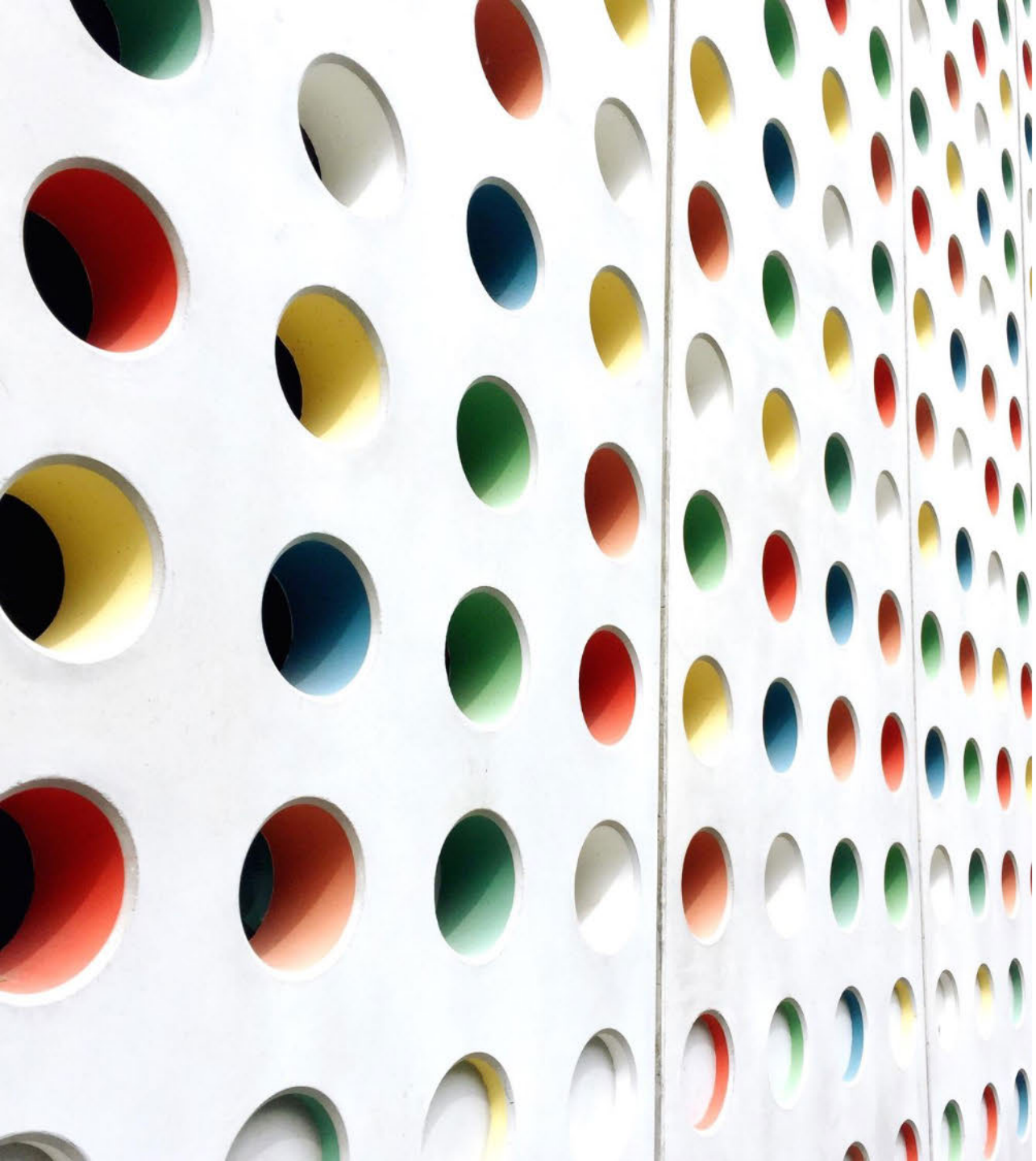


The Alliance for Sustainable Management of Chemical Risk

JOINT MEETING WITH DG GROW AND DG ENV

28 NOVEMBER 2022

Agenda

- Introduction of ASMoR
- Exchange on a specific aspect of the Reform:
  - Generic Risk Approach and Essential Use Concept
  - Point of particular attention: Need for derogations for safe (not only essential) uses
- Exchange on the overall Reform of chemicals risk management
- Conclusions

Introduction of ASMoR

AS_MoR The Alliance for Sustainable Management of Chemical Risk -signatories

The Generic Risk Approach and the Essential Use Concept

Considerations regarding the Application of the Essential Use Concept

TARGETED USE WHERE OTHER RISK MGMT OPTIONS WERE CONSIDERED INSUFFICIENT

- Montreal Protocol (ozone-depleting substances)
- Biocides Regulation

SWEEPING USE PROPOSED UNDER THE CHEMICAL STRATEGY FOR SUSTAINABILITY (CSS)

- Proposal to ban all ‘Most Harmful Chemicals’ (MHC) in consumer and professional articles
- Exemption to be permitted only for essential uses
- Even uses that do not lead to exposure and are safe would be prohibited

Regulatory Purpose 1: Speeding up Regulation

Some perceive that chemicals **risk management** is currently too slow. They argue that a **blanket ban** with possible exemptions for essential uses will be **"faster and simpler"**

Our perspective:

- We recall that when REACH Authorisation was set up, the argument was similar. It was thought that the process would place the burden on industry and be simple for authorities. This has not been the case.
- GRA/EUC would require authorities to review all applications for irrelevance - **extremely granular and extensive assessment**. Even for applications where the authorities have reliable information that they are safe and useful.

GRA/EUC is not a panacea for regulatory efficiency. Realistic impact assessment is needed.

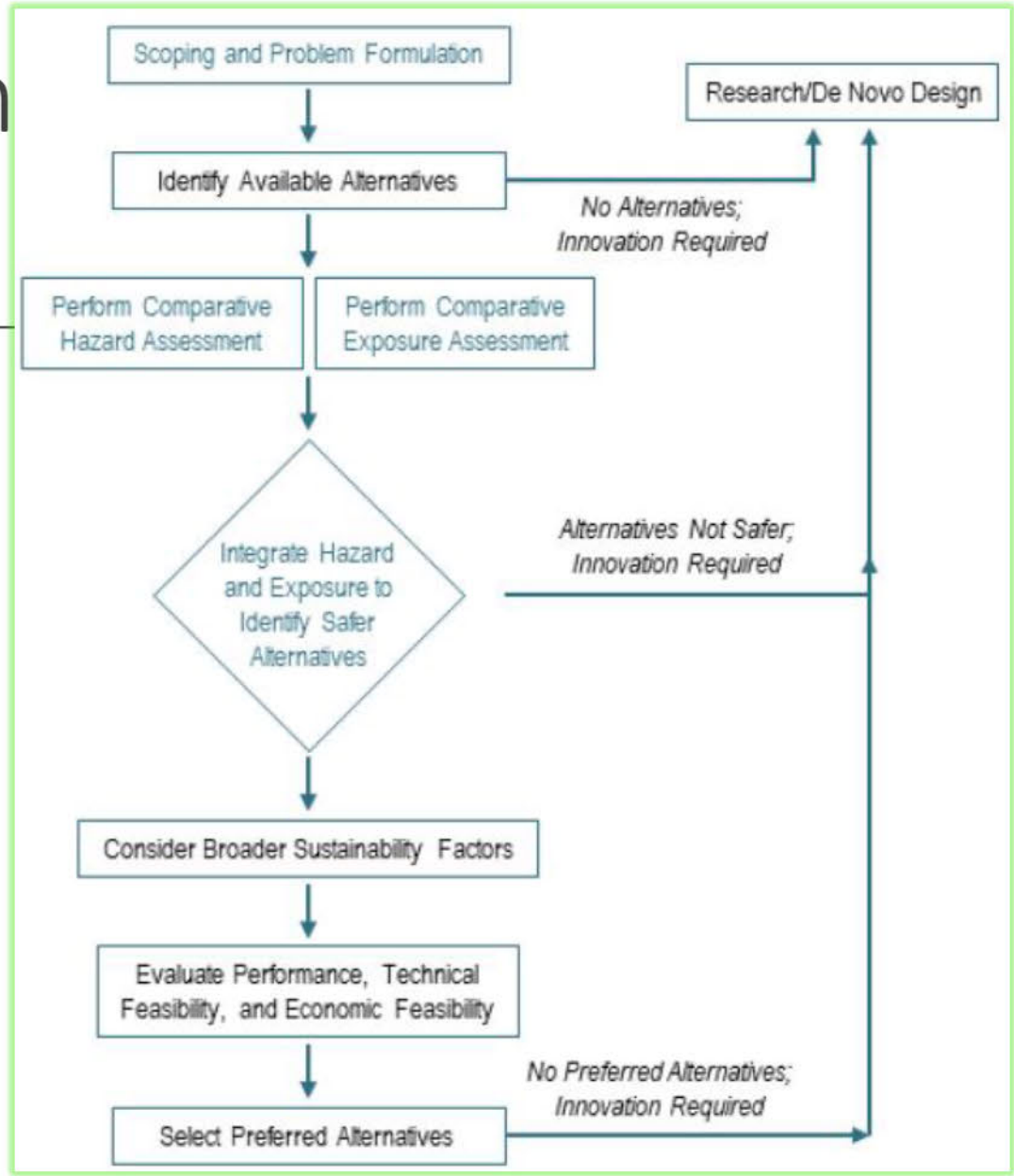
Reg. Purpose 2: Promotion of Substitution of MHCs

Some perceive that substitution of hazardous substances has not progressed fast enough → aim to put stronger pressure by means of generic bans with derogations only for essential uses

Our perspective:

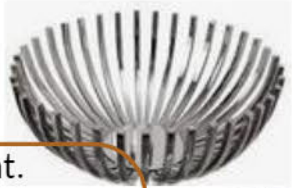
- Informed substitution requires an assessment of more than hazard information
- Hazards perceived to be lower and thus not in the scope of MHC may lead to an actual risk, where the MHC may currently be used safely.
- Alternatives may be available, but be more problematic than the MHC from a climate change, circularity or other perspective

A ban simply based on hazard runs the risk of promoting regrettable substitution.

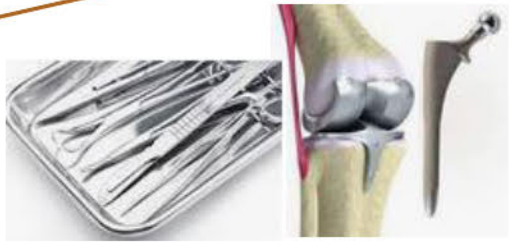


Source: OECD Guidance on Key Considerations for the **Identification and Selection of Safer Chemical Alternatives, 2021**

A glimpse of the workload for assessing essentiality claims: A selection of uses of one of the concerned substances – Nickel



Stainless steel is considered to be corrosion resistant. Nevertheless it releases low amounts of nickel and chromium. The release is highest in new food contact materials and decreases over time. The release from stainless steel into food is negligible compared with the natural contents of these elements in food, considering an average daily diet.
(Guidance of the Nordic Council on Food Contact Material)



Possible disproportionate impact of GRA on substances that may be classified in the future – example of silicone sealants

Upcoming classification

There is a proposal to classify silicon dioxide as STOT RE 1, H372 (repeated dose toxicity via the inhalation route of exposure). This will classify silicon dioxide as a 'most harmful chemical' according to the Chemicals Strategy for Sustainability (CSS) definition.

Safety of use

The silicon dioxide proposed classification of STOT RE 1 relates only to the physical hazard in dust form when inhaled, not to a chemical hazard. Silicon dioxide in silicone sealants is inextricably bound in the polymeric matrix and cannot be inhaled

Environmental and social benefits

Efficient building insulation for energy savings

- Buildings consume more than 40% of energy in Europe
- Insulation technologies like silicone sealants can reduce energy costs associated with buildings with as much as 60%

Extension of the life span of buildings

- Insulation techniques mitigate natural and man-made disasters and promote climate adaptation
- Sealants protect sensitive materials from water penetration

As a consequence of GRA, silicone sealants could no longer be used by consumers and professionals.

Adjustments considered by the COM: safe uses and a more targeted approach

CARACAL papers of EU Commission of 2022:

"If there are indications that certain use in articles can be considered "safe" during the life cycle of the articles, this could in principle be taken into account in risk management measures, in particular for articles. The impact assessment will [...] assess how the essential use concept could be combined with the ***concept of safe use****."*

Developments since the above quotation: (1) safe uses → uses with minimal exposure;
(2) exemption requests with safe use/use with minimal exposure are not considered necessary.

"the priority remains to first restrict substances on their own and in mixtures, although restrictions of (<u>some</u>) substances ***<u>in selected types of articles</u>*** *may be proposed"*

What is the status of the discussions about a possible use of the safe use / minimal exposure concept?
Can it be a reson for upfront exemptions and/or derogations upon application?

What are criteria under consideration for exempting some substances from GRA approaches?

Derogations for minimal exposure

Concept, as formulated in the GRA-survey: "Derogations from restrictions and/or authorisations granted if it is proven that emissions/exposure for uses of substances in articles **and for industrial uses** of substances in mixtures are absent/minimal **throughout the lifecycle** AND there are **no suitable alternatives**. "Minimal exposure" route"

ASMoR supports this derogation route in principle, but **suggests two changes** to it:

- **Demonstration of minimal exposure in the life-cycle**
  - **Not the entire life-cycle should be considered, but only the actual use by the consumer (or professional)**
  - ➢ **We object to a broadening of the GRA and EUC concept to life-cycle phases that are covered by OSH.**
- **Availability of no alternative**
  - **Where safety for both HH and ENV is ensured, the derogation should be granted regardless of alternatives that may or may not be available. If not the workload for ind + authorities would increase and regrettable substitution may be promoted**

The Revision of Chemical Risk Management should contribute to the Green Deal objectives

- There appears to be a lack of consideration on how the revision of chemical policy (in particular a shift to hazard-based approaches) negatively correlates to other policy objectives (e.g. the reduction of greenhouse gas emissions / prevention of climate change, circularity or other sustainability considerations).
- Furthermore, chemicals policy does not seem to sufficiently take into account other EC policy objectives, e.g. related to the resilience and strategic autonomy of EU markets (as outlined in the EU Industrial Strategy)

Questions – Essentiality

- What will be the further process in establishing the definition of essentiality?
- Regarding Analyses of Alternatives in the essentiality context
  - We understand that the acceptability of the alternative from the standpoint of environment and health will be considered. Does “environment” cover also an assessment of non-chemical impacts of the use of the alternative (sustainability)?
  - What about other trade-offs (e.g. loss of strategic autonomy due to broad prohibitions of a substance)?
  - What are the criteria for appropriateness of sufficient effort to prove the non-existence of alternatives?
-

Questions – Hazard-based approach and prevention of regrettable substitution

- Have you considered how to avoid negative trade-offs when pushing for substitution simply based on hazard?
  - The push for substitution of MHCs in essential and safe uses will be so strong that industry will need to substitute even when it leads to
    - Increased chemical risk
    - Trade-offs for other objectives
- ASMoR believes that upfront exemptions (based on screening) and further derogations (other than for essentiality) upon application are necessary
- How will prioritisation be informed, if screenings for likelihood of risk / essentiality are not done upfront?

Questions – EUC and other legislation

Taxonomy:

- On 3 August 2021, the Platform on Sustainable Finance ('PSF') published a draft Technical Report and its Annex on preliminary recommendations for technical screening criteria for the EU Taxonomy environmental objectives 3 – 6. These documents reference to the EUC, which is still not defined/developed under EU chemical legislation.
  - The same applies to the already adopted EU Taxonomy Climate Delegated Act (establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation), where the essential use concept appears under the Annex I and Annex II (Technical screening criteria for climate change mitigation and adaptation in DNSH). The essential uses criteria are currently under development and there is no definition yet of "essential uses" beyond the one used in the Montreal Protocol, limited in scope. However, referencing already in Taxonomy to the EUC will limit the eligibility of numerous sectors and hamper innovation, both being detrimental to the achievement of the European Green Deal goals.
  - ASMoR, therefore, already in December 2021 recommended that the Commission Platform avoids proposing measures on the basis of developments which remain undefined as of yet, or subject to ongoing legislative debate – in this case, the revision of existing chemicals legislation. Instead, we suggest applying the Better Regulation principles for the achievement of political goals.

Does the Commission consider steps to avoid hampering eligibility of safe materials under Taxonomy and ensuring that the development of "essentiality" is not detached from that under chemicals policy (e.g. possible recognition of derogations for safe uses)?

The reform of risk management

Proposed Reform of the Candidate List

PROPOSED FURTHER LEGAL CONSEQUENCES OF INCLUSION IN THE CANDIDATE LIST (E.G. REPORTING OBLIGATIONS FOR DOWNSTREAM USERS, FEES, ETC.)

- If candidate listing has too many different legal consequences, it cannot be used in a targeted fashion.
- Better tools than the candidate list should be identified to trigger information from downstream users (DUs). (e.g., the PACT under "Assessment of Regulatory Needs").
- Data collection should be limited to information that is relevant. The timeframe for providing data should be limited.
- We argue against a dynamic link between CLP and the candidate list.
- The MSC could carry out a relevancy assessment before adding a substance (or specific uses of a substance) to the candidate list.

Proposed Reform of the Candidate List

PROPOSED FEE SYSTEM FOR SVHCS

- We oppose the introduction of a general fee system for SVHCs.
- It would be a continuous tax on the safe use of SVHCs where there is no alternative and where the use may even be essential for society

LIST OF ALTERNATIVES

- We are against the introduction of a list of alternatives
- There is rarely "one" alternative for the use of "one" substance.
- The analysis must be use-specific and a list of alternatives for a substance would be too simplistic and misleading.

Policy options

POLICY OPTION 1

- We believe that the proposals in the CARACAL paper would not make the authorisation process more workable.
- We propose to use the above-mentioned relevancy assessment to include the option to limit authorisation to specific uses of SVHCs where authorisation could really make a difference. This would also ensure that the workload is manageable for authorities.

COMMENTS RELEVANT FOR ALL POLICY OPTIONS

- The choice of risk management option should not be based on classification alone.
- We advocate an early RMOA / Assessment of Regulatory Needs.
- Art. 68 para. 1 could be revised to better distribute the burden of proof between authorities and industry.
- We call for a better integration of REACH with other EU legislation (criteria for the selection of RMOs should be defined).

Questions

- What is the status of considerations on the Candidate List and the multiple functions that were considered to be assigned to it?
- What is the current thinking about how to combine different elements of the policy options?
- Has the Commission integrated suggestions made by MS / stakeholders (e.g. ASMoR on a reform of Authorisation / Article 68(1))? What do you think about these alternative reform ideas?

ASMoR Recommendations for the way forward

Our recommendations

Recommendation 1 regarding derogations:

- There should be **generic derogations** (granted by authorities after screening process). For the rest, derogations may be granted based on applications. (gain in efficiency, compared to derogations only based on application).

Recommendation 2 regarding derogations:

- **Two derogation routes** should exist: (1) for **safe uses** (/uses with minimal exposure); (2) for **essential uses**

In particular **for articles, Art. 68(2) restrictions** should be used as a **last resort**, i.e. only where there is a risk / concern that cannot be addressed by more targeted RMOs. Targeting of sectors would help in this regard.

An **early screening process (RMOA)** could help define an appropriate scope and generic derogations, which would lighten the workload for both industry and authorities.

Further ASMoR recommendations

- **Object** to the proposed broadening of the GRA to also **cover industrial uses**
- **Professional uses should not all be subjected to GRA**.
- We support the inclusion of concentration limits, but stress that for some substances **release limits** are more appropriate.
- The **burden of proof** regarding alleged **alternatives** should be **more fairly distributed** (who claims that there is an alternative should be required to provide sufficient information to assess it)

Questions

- Timeline and process
  - At the CARACAL meeting 2 proposals have been announced:
    - PROPOSAL 1: via comitology procedure (fast-procedure) for REACH Annexes + Restriction Art. 68(1). What are the other aspects included?
    - PROPOSAL 2: via ordinary procedure – will this proposal contain the major changes to the legislation (Auth+Rest+GRA+EUC)?
- New engagement opportunities
  - Follow-up material

Contact us

ASMoR Secretariat

[redacted]@hanovercomms.com

[redacted]@hanovercomms.com

[redacted]@hanovercomms.com

How ASMoR sees the GRA + EUC fitting into EU Chemicals Risk Management

Prioritisation of (group of) substance(s) of concern

Initiation of RMOA

Screening assessment of uses and related exposure

Differentiation between safe and other uses

Identification of safe uses

No regulatory action (to be exempted from scope of possible RMO)

Other uses

Identification of areas where risk / concern arises

Screening assessment of socio-economic aspects (including essentiality) and of AoA data

Uses posing an acceptable risk / level of concern (e.g. based on essentiality considerations)

Uses with unacceptable risk / level of concern

Can risk / concern be addressed by targeted RMO(s)?

Yes

Targeted RMO(s)

No

GRA-based ban (uses already demonstrated as safe or essential to be exempted, further exemptions can be granted based on successful applications for derogation)

AS_MoR The Alliance for Sustainable Management of Chemical Risk