EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Ecosystems I: Chemicals, Food, Retail
F1. REACH

Brussels
GROW.F.1/OL

BACKGROUND PAPER
WORKSHOP ON THE REFORM OF THE REACH AUTHORISATION AND RESTRICTION SYSTEM

1. THE PURPOSE OF THE WORKSHOP AND THE COMMISSION'S EXPECTATIONS

This workshop is intended to inform and familiarise stakeholders with the initial thinking of the Commission services on the planned reform of the REACH authorisation and restriction system announced in the Chemicals Strategy for Sustainability, as well as other elements that will be assessed in the impact assessment. It is also intended to get initial reactions from stakeholders, to help refining the policy options and to inform the Commission's impact assessment.

The Commission invites the participants to **provide feedback to the questions** indicated in **section 5** during the 'world café' tables. As each table has only 30 minutes to discuss each of the questions, and the intention is to get feedback from as many participants as possible, it will be important that such feedback is synthetic and to the point.

While the opening and closing sessions of this workshop will be web streamed[1] and made accessible to any registered stakeholder, the world café tables will be accessible only to the participants of that table[2]. Any views expressed there will be kept confidential and only a summary of the discussion, without naming individual stakeholders will be reported in the closing session.

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

Stakeholders are also invited to contribute to the Open Public Consultation (tentatively planned from December 2021 to March 2022), as well as to the targeted consultations in the form of questionnaires, possibly followed-up by specific interviews. The Commission will also be supported in this work by a study contractor[3]. Stakeholders can express their interest to participate in the targeted consultations and are also invited to submit written contributions to the Commission to the following e-mail address: GROW-ENV-REACH-Revision@ec.europa.eu at any stage of the process.

[1] For registered participants attending remotely, the links will be communicated closer to the meeting.
[2] For participants attending world café tables remotely, the links will be communicated closer to the meeting.
[3] The terms of reference will be sent out to workshop participants along with this background document.

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2. BACKGROUND

The 2018 REACH Review[4] concluded that REACH is effective, but that there are opportunities for further improvement, simplification and burden reduction. In its conclusions, the review identified a number of actions to improve the implementation of REACH, including on authorisation and restriction. However, it did not identify a need to change its enacting terms, inter alia because of the (at that time) still ongoing implementation of key milestones of the REACH Regulation, such as the final registration deadline for phase-in substances.

In 2019, the Commission adopted the European Green Deal[5] as the core of its policy objectives. As part of a zero pollution ambition, the European Green Deal announced the Chemicals Strategy for Sustainability[6], including initiatives to simplify and strengthen the legal framework to better reflect and address risks by the most harmful substances. The Chemicals Strategy for Sustainability announced a targeted revision of the REACH regulation, including a reform of the REACH authorisation and restriction process in the light of the findings of the 2018 REACH Review. Possibilities for reform of the authorisation and restrictions processes will be the focus of this workshop.

The Chemicals Strategy for Sustainability (CSS) also announced extending the generic approach to risk management (i.e. in REACH, Article 68(2)) to further hazard classes and uses. This generic approach to risk management means that the procedure under Article 68(2) can be used to restrict the most harmful chemical substances in products for consumer and professional use, while allowing limited exemptions under conditions clearly defined in the law. Possibilities for extending the generic approach to risk management will be addressed in a separate workshop and will, therefore, not be discussed further in the present document.

3. PROBLEM DEFINITION - THE COMMISSION´S INITIAL ANALYSIS

3.1. Authorisation process

The 2018 REACH Review concluded that authorisation is meeting its objectives but that implementation should further gain in efficiency and aim to further reduce administrative burden and business uncertainty for companies applying for authorisation, in particular for SMEs.

The inception impact assessment outlined that: *'The authorisation procedure is too heavy and inflexible. The authorisation process has imposed a heavy burden on both companies and authorities. A multitude of applications for the use of small quantities of substances, unclear criteria for authorisation and information gaps (in particular for uses where competitors have already implemented alternatives), as well as unclear information in applications (in particular from applicants up the supply chain and from only representatives) have led to prolonged discussions and delays in decision making. In many cases, this has placed EU-based companies at a competitive disadvantage compared to their non-EU competitors.'*

[4] EUR-Lex - 52018DC0116 - EN - EUR-Lex (europa.eu)
[5] EUR-Lex - 52019DC0640 - EN - EUR-Lex (europa.eu)
[6] Strategy.pdf (europa.eu)

3.1.1. Achievements

Many companies have substituted substances of very high concern (SVHC) after their inclusion in the candidate list or Annex XIV, drastically reducing the quantities and numbers of uses of the concerned substances. Moreover, the risks stemming from the remaining uses are better controlled[7]. By inverting the burden of proof, the authorisation process has also led to a very substantial increase of information that can be used to assess the need for the continued use of substances of very high concern, to enquire about substitution possibilities as well as to improve risk management.

Thus far, no applications have been received for almost half of SVHCs on Annex XIV, which means that these substances can no longer be used in the EU. The emission of endocrine-disrupting substances were projected to decrease by over 90 % in 2032 while preserving societal benefits of some €6 billion per year. The societal benefits from continued use of SVHCs were estimated to be almost 20 times larger than the monetised health risks.

According to the latest ECHA study[8], five years after the entry to Annex XIV, Swedish firms had reduced their annual use of SVHC requiring authorisation by about 40%.

3.1.2. Challenges

Feasibility and workload

Authorisation has been a major challenge for applicants and authorities, in particular relating to:

- "Upstream applications" covering several hundreds of downstream users have turned out to be problematic, as the applicants had in practice limited insight into the uses, operational conditions, risk management measures and possibilities for substitution at downstream level.
- Where downstream users applied individually, this sometimes created a multitude of often repetitive individual applications for similar uses of sometimes very small quantities of SVHCs (e.g. uses of OPE and NPE in pharmaceutical production and medical applications; there is also an increasing number of new applications for chromium(VI) substances used for chrome plating). Moreover, this raises a consistency problem for applications and may give an advantage to late applicants who can benefit from the experiences of those applying earlier.
- The type and amount of required information is a challenge for small and medium sized companies, which often do not have the knowledge or capacities in generating that information (e.g. dependence on suppliers, technological choices of their clients, toxicological information, socio-economic analysis, etc.).
- The type and amount of information to be submitted and the complexity of the aspects to be considered in the decision making is also a major challenge for companies and authorities, and has led to controversies, court cases, and subsequently considerable delays in the decision-making, with the associated uncertainties for companies. The main reasons are:

[7] Socio-economic impacts of REACH authorisations - A meta-analysis of the state of play of applications for authorisation. ECHA April 2021 available at https://echa.europa.eu/documents/10162/13637/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4

[8] Causal impacts of the REACH Authorisation process on the use of substances of very high concern in the EU. ECHA. 2021 (forthcoming)

- REACH authorisation is based on the concept of "uses". In reality, a use as applied for can embed a multitude of different sub-uses (called "utilisations" in authorisation decisions), which all have their own characteristics in terms of applied risk management measures, but also in the suitability of alternatives.
- The detail of required information for uses is a critical factor to determine the feasibility of the authorisation process, not only for applicants but also for authorities. For example, in one airplane a specific part produced with an alternative technique to the use of chromium(VI) might work, whereas in another airplane the same part might only work if plated with chromium(VI) (e.g. because the part might be exposed to corrosion in one airplane but not the other; or simply because airplanes using alternative substances/techniques would still need to undergo airworthiness procedures). Assessing all those detailed choices for a wide range of utilisations is *de facto* impossible.
- Another factor that has proven critical is the acceptable loss of performance. The alternatives may not provide the same level of performance, which in some cases may be acceptable but in others may result in severe problems, e.g. for the safety of equipment, product durability or energy efficiency. REACH in its current form does not give any guidance, which makes such decisions very difficult.
- For substances that can only be authorised through the so-called socio-economic route, the socio-economic benefits of continued use of substances of very high concern have to be weighed against their associated risks. However, the risks and the benefits cannot always be quantified, comparison using monetisation becomes difficult and a more qualitative analysis is required, including comparison of private and societal costs and benefits, often incurred by different actors. Some of the relevant trade-offs are related to societal preferences, e.g., society may not be willing to accept health risks from the production of luxury articles, such as chrome-plated lipstick casings. At the same time, it seems unnecessary to require detailed proof of benefits outweighing the risks where essential uses such as the production of vaccines are at stake.

Dealing with such a high amount of often very detailed information, complex assessments, controversies and court cases, binds significant resources from ECHA, the Commission and Member States. As a consequence, those resources are not available to deal with other, potentially more important concerns. This is one of the key reasons, if not the main reason, for delays in adopting authorisation decisions (which in turn also delays necessary risk management measures and substitution of chemicals). It also impedes progressing with restrictions, many of which have been delayed due to resource constraints.

Moreover, due to the complexity of the authorisation process, industry has been arguing in favour of alternative risk management measures such as restrictions or occupational health and safety measures where they perceive less uncertainties and administrative burden. This has also affected the choice of risk management measures by authorities. Following the experience with chromium(VI) substances, no other SVHC with a similar widespread use has been recently added to Annex XIV. Risk from widespread use of such substances have been, or are being addressed more recently rather through the restriction procedure (e.g. PFAS substances) or through occupational health and safety measures (e.g. cobalt and its compounds, lead and its compounds), and the extension of generic restrictions will further reduce the number of potential substances and uses that could be subject to authorisation. As a result, what remains under the authorisation process, is of decreasing relevance for the overall management of chemical risks, since many substances that have recently been added to Annex XIV have limited or no uses in the EU.

Subsidiarity

Some of the authorisation applications concern companies operating mostly in one Member State, where the associated risks essentially concern workers in that company or the surrounding environment, including the local population. The effects of such authorisation decisions on the EU internal market and fair competition (e.g. potential relocation of production to Member States with less strict requirements; price effects on final goods) are often minor, as there are only few sites with the same use(s), or the quantities of substances used are minor, and moving production would require substantial investments. For such uses, authorisation at EU level is a heavy process, and the need to involve ECHA, the Commission and other Member States is questionable.

Level playing field for EU-based companies

The authorisation process only applies to uses in the EU. This has created disadvantages for EU-based companies compared to their non-EU competitors who are not subject to authorisation, in particular when the substance is not present in the final product (hence the final product can be produced outside the EU without the need for a REACH authorisation). Although sometimes, a level-playing field can be established through introducing restrictions via the procedure of Article 69(2), this is not possible when the concerned substance is not present in the final product, e.g. chrome plated articles, or where the presence of the substance in the final product does not present a risk. In such cases, there is a risk that the production could move in future to third countries where the risks associated with the production may be less well handled, only to import the finished product back into the EU.

Insufficient incentives for substitution

Many companies have substituted SVHCs on the candidate list and in Annex XIV before the sunset date to avoid the need for authorisation. Nevertheless, companies who have submitted an authorisation application have weak incentives to enter into a dialogue with alternative providers, as this would undermine their case.

The current authorisation system is based on the suitability of alternatives at the time of authorisation. In reality, innovation is a process which constantly provides new opportunities to substitute SVHCs. Therefore, where authorisation decisions do not recognise emerging alternatives, which are not yet available at the time of authorisation or for which there are insufficient production capacities at the time of the application, there is a risk to at least temporarily cement the *status quo* rather than giving the necessary incentives for substitution.

At the same time, the innovation process is also full of uncertainties. Alternatives which work in certain conditions may not work in other conditions. Loss of performance may be acceptable in some but not all uses/utilisations. Initially promising alternatives may or may not be confirmed to be suitable in large scale production.

3.2. Restriction process

The 2018 REACH review concluded that the efficiency of the REACH restriction process has so far not met original expectations and that there is room for improvement. A key element is the significant requirements linked to the preparation of restriction proposals, which put a major challenge to authorities.

The inception impact assessment outlined that: '*The current restriction process is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances. The normal restriction procedure, through specific risk assessment, puts a high burden on authorities to document unacceptable risk for health or the*

environment. Although REACH already enshrines the use of a generic approach (i.e. assuming that the use constitutes a risk) for restricting certain carcinogenic, mutagenic or reprotoxic (CMR) substances in consumer products, this procedure cannot be used for other critical hazard classes including endocrine disruptors, persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances, immunotoxicants, neurotoxicants, respiratory sensitisers or substances that affect specific organs. Moreover, professional users are often using the same products as consumers, but much more frequently and during longer periods of time. Yet, they are unlikely to benefit from the same risk management as in industrial settings. Hence, they should get a level of protection at least at the level of consumers.'

3.2.1. Achievements

Restrictions have for a very long time been a key tool to manage unacceptable risks relating to the use of hazardous chemicals. The REACH Regulation has brought a more structured approach and a more consistent assessment of risks under the procedure following Article 68(1) and has extended the use of generic restrictions following Article 68(2) to specific articles (e.g. textiles). ECHA summarised the achievements of the restriction process in 2021[9].

3.2.2. Challenges

Burden of preparing restriction proposals

The burden upon authorities to prepare restriction proposals under Article 68(1) is significant. Member States do not always have necessary staff resources and access to key information, in particular in relation to uses and exposure as well as technological choices and alternatives. This has limited the readiness of Member States to make restriction proposals, and focused restrictions to substances and uses where information was available. As a consequence, the pace of restrictions has been slow compared to expectations and some emerging risks have not yet been addressed. The tendency of restrictions to increasingly address broader groups of chemicals has helped to increase speed and regulatory efficiency, but this also makes the dossier development more comprehensive. Although restrictions under Article 68(2) do not have explicit information requirements, in practice information gathering for uses in articles has also been complex and taken considerable time.

"Regrettable substitution"

The consequence of limiting restrictions to "information-rich" substances, and of proceeding restrictions substance by substance has led in certain cases to "regrettable" substitution (i.e. replacement of a restricted substance by other non-restricted substances with similar properties, for which less information was available). Examples are the use of alternative PFAS substances after the restriction of PFOA, or the substitution of bisphenol A by bisphenol S in thermal paper. This has been partly addressed by the move to broader restrictions (e.g. broad PFAS restriction under development, restriction proposal for substances in clay targets) but remains an issue to be closely observed.

[9] Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA. 2021. Available at https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e

Lack of information for grouped restrictions

To avoid the problem of regrettable substitution, more recent restriction proposals tend to be broader and group a wide range of substances and uses, e.g., the upcoming restriction proposal on PFAS substances. Such group restrictions require substantial efforts from authorities to gather and assess information, including on justification for grouping, uses and possible alternatives. They may also create challenges in terms of properly defining the scope of the restriction, and as regards enforceability (need to test for a wide range of substances; need for analytical methods; unclear terms that need to be defined etc.). Next to the burden on the resources of authorities, lack of adequate information makes it difficult to assess in all necessary detail whether derogations are justified. If such information is not available or insufficiently assessed, there is a risk that certain derogations are proposed unnecessarily and others are not included in the dossier despite a societal interest.

Lack of information on use and exposure of the most harmful substances

Registration dossiers contain certain information on the types and broad categories of uses. Where a chemical safety assessment is required, there is also information in chemical safety reports on how the registrant ensures that the exposure is below safe levels. During the preparation of restriction proposals authorities often organise calls for evidence to gather the necessary information from companies and other interested stakeholders. However, there might be a lack of incentive for companies to provide the required information on uses (including use volumes) and exposure/emissions, because of concerns that their submission may result in legal action by authorities. Therefore, information on use and exposure available to authorities is often relatively general, and it is impossible to identify the exact uses and exposure patterns of the substance.

Enforcement and enforceability

There is widespread agreement among stakeholders that enforcement of REACH, including restrictions, is a key area requiring improvement. While enforcement as such is the matter of other actions within the REACH revision and the Chemicals Strategy for Sustainability, there is also criticism that many of the provisions of REACH authorisation decisions and restrictions are difficult to enforce.

Disproportionate impacts on SMEs

Like for authorisation, SMEs have difficulties to keep up with restrictions, to prepare relevant contributions to consultations and to adapt to new restrictions.

3.3. Interface with other EU-legislation

Many interfaces between REACH and other pieces of legislation work well. However, in some areas there are regular debates on which legislation is the more appropriate to address health or environmental risks. Revising the REACH regulation is a once in a decade opportunity to discuss those interfaces and to see whether those interfaces can be regulated better.

The interface that most regularly leads to discussions in the context of REACH authorisation and restrictions is legislation on occupational safety and health (OSH legislation). This has been discussed and analysed in several papers, the most recent ones being CARACAL paper CA/64/2020 and an opinion by the Advisory Committee on Safety and Health at Work on the interface between EU OSH Legislation and REACH restrictions (Doc. 2276/20). Those documents give recommendations on which of the two legislative areas to choose in what cases.

Whereas REACH is based on Article 114 of the Treaty (i.e. measures to ensure the good functioning of the Internal Market in the areas of protection of health, safety, environmental protection and consumer protection), OSH legislation is based on Treaty Article 153 (improvement in particular of the working environment to protect workers' health and safety). Although article 153 is more specific on worker's health protection, REACH has also been used in the past to ensure the protection of workers in some specific cases. However, relevant measures follow different procedures. While REACH is based on full harmonisation, and most practical measures are adopted under comitology, OSH legislation sets minimum requirements at EU level, involves the consultation of social partners, and most practical measures are taken by the co-legislators. Such measures also require transposition into national legislation.

One key overlapping area for threshold substances is the setting of Occupational Exposure Limits (OELs) under OSH legislation and Derived No-Effect Limits (DNELs) under REACH. Both limits set maximum exposure limits to workers. They both take into account scientific information on the hazards of substances and their effects in case workers are exposed. For non-threshold substances, the Commission has started preparatory work on Derived Minimum Effect Levels (DMELs), for which the interface with OSH legislation would also need to be carefully assessed and discussed. Under OSH legislation there is a well-developed system for adopting OELs for non-threshold carcinogens. In recent years this has been used to adopt new, or revised, OELs for a significant number of priority occupational carcinogens.

Under REACH, DNELs are set by registrants who have the obligation to ensure that in the entire value chain no uses are supported where the DNEL would be exceeded. As the derivation of the DNEL is a task for the registrant, sometimes there are divergences between different registrants or between registrants and authorities, and in certain measures, e.g. ECHA opinions on authorisation applications or in certain restrictions for threshold substances, the ECHA risk assessment committee derives a particular reference DNEL value. This reference value is then used as the basis for its assessment, and for proposing risk management measures in its opinions. In order to address these divergences more systematically, the setting of harmonised DNELs is currently being discussed under the revision of the CLP Regulation.

Under OSH legislation, 'indicative' or 'binding' occupational exposure limit (OEL) values (IOELVs and BOELVs, respectively) are occupational standards established, in the case of IOELVs, on the basis of scientific and technical advice or recommendations from the ECHA Risk Assessment Committee and, in the case of BOELVs, by taking also socio-economic and technical feasibility factors into account.

In cases where DNELs and OELs (in particular BOELVs) diverge, this creates confusion both for companies which have to apply both values, and for enforcement authorities. Therefore, in the past there have been attempts to recommend when one or the other route to set binding values should be preferred. Nevertheless, this has not eliminated the overlaps and inconsistencies entirely.

In addition, in both legislative areas, further measures to protect worker health may be taken. Under REACH authorisation and restrictions, conditions for the use of certain substances in the form of prescription of certain risk management measures as well as measurement requirements may be set, which very often relate to the workplace. Some authorisation decisions set detailed rules on how to manage substances at the workplace, by making the applicant's risk management measures described in the exposure scenarios of the application a condition for the authorisation or by directly imposing certain additional measures. Although those decisions apply without prejudice to existing EU and national workplace legislation (and in particular additional national requirements may

continue to exist), they de facto become minimum workplace standards in the concerned installations. There have been discussions whether maximum exposure limits should be specifically spelled out in certain REACH authorisation decisions. This would be very similar to BOELVs. However, this approach was in the end not retained. Some of the more recent REACH restrictions set a harmonised DNEL (NMP and N,N-dimethylformamide) or training requirements (diisocyanates), which cover areas that traditionally have been addressed under OSH legislation. The reasons for taking measures under REACH vary and are not always consistent.

At the same time, for some substances such as cobalt salts, initially REACH authorisation has been recommended. When further analysis showed that authorisation would not be the most appropriate tool, a restriction dossier was prepared. After further analysis, restriction as well was found not to be the most appropriate tool, and finally setting of a BOELV was considered to be the most appropriate regulatory management option. In this case, although measures could have perfectly fit into REACH, they were replaced by measures under OSH legislation which was considered as more appropriate to protect workers. This long debate has also led to delays on both REACH and the OSH side.

In conclusion, there is a strong overlap between measures intended to protect workers under REACH and under OSH legislation. In the past the choice of either instrument has been inconsistent and has not followed a strong logic but has rather been driven by timing, practical and *ad hoc* considerations. It is desirable to discuss whether a more co-ordinated and potentially integrated approach could not better address such risks.

Another interface worth mentioning in the context of REACH authorisations is the Industrial Emissions Directive, in particular as regards emission limits and monitoring for industrial installations, which are often part of permits under national legislation. Also in this area, there could be some inconsistencies and overlaps as recently exemplified on the authorisation cases for octyl- and nonyl-phenol ethoxylates in uses to produce pharmaceuticals. Other examples include the interface with water and waste legislation (e.g. ongoing discussions in Council on the Batteries Regulation).

Finally, as regards a series of specific product legislation, such as on cosmetic products, toy safety, food contact materials etc., where some overlaps and inconsistencies could also be identified, those are not aimed to be addressed in detail at this workshop. Nevertheless, participants are welcome to identify issues they consider of particular importance.

3.4. Conclusion and initial problem definition

Despite the increased protection resulting from the implementation of REACH authorisation and restriction and the benefits from creating significantly more information serving the decisions on regulatory risk management, both the authorisation and, to a lesser extent, restriction processes have created a heavy burden on involved actors.

Although the speed of assessing and regulating risks has increased compared to the previous risk assessment under Regulation 793/93, the REACH authorisation and restriction activity in the EU has been slow and lagging behind expectations. Especially the authorisation process has turned out to be controversial and subject to legal challenges, creating uncertainty and further delays in deciding on risk management measures.

Links between REACH and other legislation have not been optimised, perpetuating or creating overlaps and inefficiencies in chemicals management and hindering the realisation of its policy objectives.

3.5. Objective of the reform of the authorisation and restriction process

In the initial view of the Commission, the identified weaknesses are substantial. For this reason, the Commission announced in the CSS a **reform of the REACH authorisation and restriction processes** based on key findings from its practical implementation.

A more extensive use of restrictions with a larger scope, combined with simplifying and increasing efficiency of the processes and focusing information requirements for derogations/authorisation to what is relevant and necessary for decisions should:

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

4. OPTIONS CONSIDERED

4.1. Authorisation process

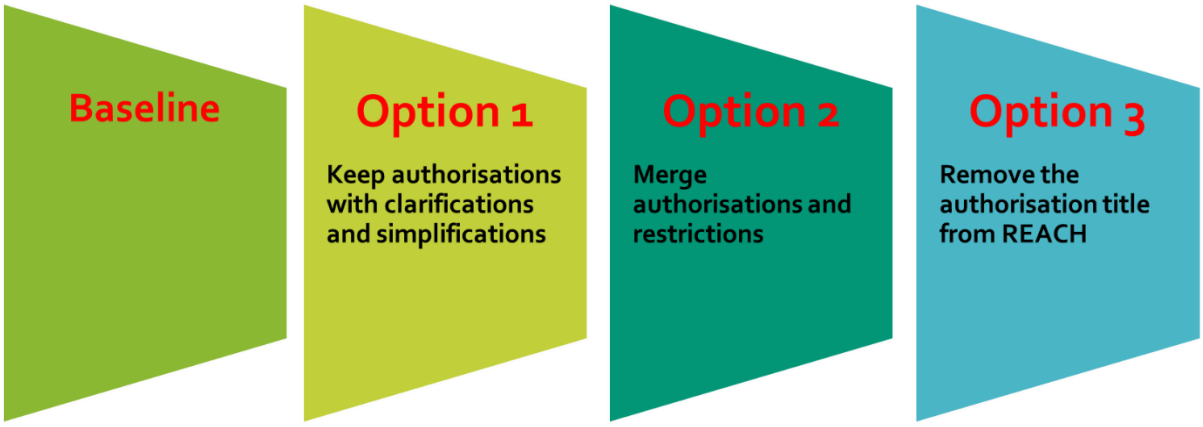
The inception impact assessment states that: *'Options include clarifications and simplifications of the current provisions, national authorisation for smaller applications, removing the authorisation title from REACH, integrating the REACH authorisation and restriction systems into one and improving the interface with other pieces of legislation (complementing actions under the one-substance one-assessment action under the Chemicals Strategy).'*

4.1.1. Main options

To better structure the impact assessment, the Commission has identified four main options, including the baseline option, which is the current REACH Regulation implemented as of April 2021. Those options shall help assessing the overall degree to which the authorisation and restrictions system should be reformed. Therefore, those main options will be discussed upfront, before going into other, more specific sub-options (see section 4.1.2). As those main options are fundamental to determining the extent of the planned reform, they will be at the centre of the discussions at the workshop. They are mainly designed from the point of view of authorisation because in the view of the Commission services, there is a higher need to reform the authorisation system, whereas the main elements of the restriction system can remain in place. Moreover, the timing and modalities of the implementation of the generic approach to restrictions will also be the subject of further workshops planned for March and June 2022, taking into account information to be gathered by the study contractor in the meantime. Nevertheless, those main links[10] to restrictions will also be part of the discussions at the workshop.

[10] In particular, there are corresponding proposals for simplification in section 4.2; option 2 addresses both authorisation and restrictions; option 3 would rely on restrictions exclusively

The following main options will be considered:



Option 1: Keep the authorisation process, with clarifications and simplifications

This option is based on keeping the existing authorisation process but modifying a number of elements to address the weaknesses identified during its current implementation. The main purpose of this option is to assess whether smaller changes of the authorisation system would be sufficient to improve the authorisation process to a degree that would be better than the alternative options.

The various elements identified below will also be assessed individually, so that in case the overall option will be retained, it would be possible to keep only some of the modifications. Moreover, there may be additional elements resulting from the work on the impact assessment, in particular from the open and targeted consultations, that might be added to this option. Finally, some of the elements assessed under this option might also be relevant for option 2.

Elements considered are, e.g.:

- Clarify procedures to introduce changes to granted authorisations, e.g. increase in volume; consider obligation to notify changes/changed circumstances during the period of authorisation, including a notification fee;
- Clarify transitional provisions for refused authorisations to allow phase out of uses;
- Consider the possibility of a fixed time limit for authorisations and a limited number of reviews/prolongations possible;
- Clarify the content and timing of notifications to ECHA by downstream users (Article 66);
- Clarify the concept, information requirements and structure of substitution plans;
- Clarify the criteria of suitability of alternatives, including when alternatives are available in general for the same or similar uses;
- Clarify the definition of “use”;
- Consider the definition of intermediates;
- Consider to define the completeness/conformity checks of applications for authorisation; identify data requirements, consider procedure, timing and actors responsible for conformity check; consider a verification of whether the use applied for is subject to authorisation to be part of completeness or conformity check;
- Review the timing of the various steps in the process and the sequence of involvement of different committees in the ECHA opinion making to allow that modifications proposed by one committee can be better taken into account by other Committees (including involvement of the Forum to review the enforceability of authorisation decisions);

- Clarify the criteria when 'upstream' applications and applications from only representatives can be accepted (including minimum information requirements, requirements for actors in the supply chain to pass information to the upstream applicant, defining of meaningful groups to ensure relevant data will be provided for the entire application);
- Consider progressive increase of requirements for authorisation holders (information requirements based on the downstream user notifications of e.g., exposure and emissions, increasing protection requirements, requirements to test alternatives, definition of substitution pathways);
- Simplify the application procedure for substances used in small quantities;
- Introduce a stop-the-clock procedure during the opinion making of applications for authorisations.

Please note: *It is not the purpose of the workshop to assess or discuss individual elements of the above list, which is there for illustrative purposes only and which may evolve over time. Rather, the purpose of discussing this option at the workshop is to discuss whether changes along the above elements would be sufficient to successfully reform the REACH authorisation system.*

Option 2: Merge the authorisation and restriction processes

This option is based on the assumption that the modifications of the authorisation system in option 1 are insufficient to address the identified weaknesses, in particular to reduce the administrative burden on companies and authorities, disadvantages for EU companies and delays in substitution and application of necessary risk management measures. At the same time, this option retains elements of the authorisation system, which were found to be useful, in particular the reversal of the burden of proof to obtain information on the justification of authorisations (which in this option would be synonymous to derogations from restrictions).

The underlying idea behind this option is to replace Annex XIV listing by restrictions of the concerned substances. For restrictions, prioritisation could be made on the basis of the candidate list but would not be limited to it[11]. In addition to the already existing possibility for derogations proposed by authorities, this option would give the possibility for industry to request derogations, where justified by an overall societal interest, either collectively for specified uses, or individually for specific companies.

This system would consist of four elements, i.e. a restriction with three subsequent options to grant derogations:

(1) A restriction of the use of (a) certain substance(s), covering all or specific uses of the substance. Such restrictions could be made for any substance. For restrictions in accordance with Article 68(1), the burden of proof of demonstrating an unacceptable risk is on authorities, and the justification will be assessed by ECHA's committees. This corresponds to the existing restriction system.

(2) An option for authorities to propose and introduce derogations from the restriction as part of the restriction proposal. The burden of proof for the justification of the derogation is on authorities. This corresponds to the existing restriction system.

(3) An option for companies/groups of companies to request a joint derogation from the restriction. The burden of proof for the justification of the derogation is on the

[11] For restrictions under Article 68(2), prioritisation would be done under the implementation of the generic approach to risk management.

applicants. This option is new and takes inspiration from other pieces of EU legislation, e.g. the RoHS Directive[12]. Under this system, once the restriction is adopted, applicants would be able to submit their derogation request where they would be required to provide a justification on similar parameters as required under the current authorisation system. Derogations would apply to uses (i.e. be independent from individual companies who have requested those derogations), and be time-limited and subject to periodic review. For example, around 70 individual applications for authorisation of octyl- and nonylphenol ethoxylates for use in the production of pharmaceuticals could be replaced by one time-limited collective derogation, applying to all users of the substance (within the scope of the derogated use). This option is new and details need to be discussed.

The most important aspects for further discussion are:

- The level of detail of information requirements for such derogation requests;
- The actors and procedure for assessing such requests and the link to the implementation of the essential use concept;
- Timing for the assessment of derogation requests. If derogations are decided after the adoption of the restriction, there is a need to define a period for submitting and assessing requests (similar to the system of latest application date and sunset date under the current authorisation system).

By placing the burden of proof on industry, this would significantly reduce administrative burden to authorities, especially if this will be based on clearer rules on the nature and level of information requirements. This could allow redeployment of resources to address a wider range of chemical risks. However, also for companies this could reduce the burden compared to the existing company-specific authorisation system, by placing the burden of proof at a more general level.

(4) An option for companies to apply for individual derogations (equivalent to authorisations under the current system). The burden of proof for the justification of the derogation is on the applicant. In essence, this option largely corresponds to the existing system for authorisation applications but some adaptations similar to those under point (3) could be considered. This option could be a last resort for cases where the continued use of a substance only concerns one or few companies or where there are specific reasons not to apply jointly (e.g. confidential business information). It would need to be discussed whether the use of this option should be subject to specific conditions.

Option 3: Remove the authorisation title from REACH entirely or partially

This option is based on the assumption that the weaknesses of the REACH authorisation system outweigh its achievements and that restrictions following the current models of Article 68(1) and 68(2)[13] can better address the risks of the use of SVHCs. In addition, the removal of the authorisation procedure would allow redeployment of resources, which would allow addressing a wider range of chemicals risk and ultimately lead to a higher protection compared to the current situation. While this option is the most radical option in terms of removing all formal options for industry to submit applications for derogations/authorisations, it would increase the burden on authorities as all necessary

[12] Directive 2011/65/EU Of The European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, in particular Article 5, Annexes III, IV and V.

[13] Where relevant, as modified in the revised REACH Regulation, in line with the Chemicals Strategy for Sustainability

derogations would have to be assessed by authorities. Industry could still make proposals to authorities, which may request information but this would be outside a formal process. This said, authorities could however use resources currently bound by the authorisation system.

4.1.2. Sub-options

Once the overall level of ambition of the reform is decided, those options will be further refined to take into account sub-options which could apply to all or several of the main options. The most important of those sub-options are:

The way to integrate the essential use concept

The essential use concept can be used as a tool to render decisions on derogations from restrictions/authorisation applications more efficient and aligned with societal needs. This concept should be applied to all of the above options, i.e. as one of the criteria to assess authorisation applications or derogations from restrictions. How to apply the essential use concept is part of another project, and will not be discussed in this workshop.

Ensure a level playing field vis-à-vis imported products

Where the regulated substances are present in the final product and cause risks, a level-playing field can be obtained through restrictions, by applying the same rules to imported products as to products manufactured in the EU. For uses subject to authorisation, the same is done through restrictions following Article 69(2). However, this can only be done if it is possible to document a risk that is not adequately controlled. Moreover, where the substance is not present in the final product (e.g. process solvents, uses of chromium(VI) in chrome plating), it is much more difficult to establish a level playing field. For such activities, production/uses might simply move to third countries and the final product will be imported into the EU. There is no straightforward solution for this problem. The Commission will assess options to apply e.g. economic instruments to support innovation projects to products manufactured with regulated substances, including imported products. However, this will necessitate a thorough checking of compatibility with trade rules and enforceability of such instruments vis-à-vis imported products. Any further ideas how to establish a level playing field are most welcome.

In this context and in line with the commitments in the Chemicals Strategy, not authorising and banning for export uses and substances banned in the EU should be considered.

Strengthen incentives for substitution

To create further incentives for beneficiaries of authorisations or derogations from restrictions, the Commission will assess the option of introducing obligatory contributions to financing substitution activities, inspired by the Toxics Use Reduction Act of the US State of Massachusetts. Such obligatory contributions could be coupled to authorisations as well as to the use of derogations from restrictions. Those contributions would be annual, as long as the concerned substance will be used, and would be paid into a fund to be used to finance co-operation projects between current users of substances and alternative providers to substitute the concerned substances. The management of the fund and the decisions on the projects to be financed could be a new task, for example for ECHA, but also other ways to manage this fund could be imagined. As mentioned above, the role of importers in such a system would also have to be considered.

Allow national authorisations for authorisation applications

Allowing national authorisations for authorisation applications or for applications for derogations from restrictions, criteria for such national authorisations would need to be set

(e.g. below a certain tonnage threshold, only covering installations on the territory of the concerned Member State, limited impact on internal market). Moreover, there would be a need to carefully assess the requirements for Member States wishing to benefit from such an option, e.g., set up of relevant common rules to frame national authorisations, including the protection of human health and the environment, set up of national legislation, appropriate administrative procedures and resources to deal with such requests, as well as the necessary mechanisms to control the appropriateness of national decisions to avoid problems with mutual recognition. Before introducing such an option, it should be analysed which of the authorisations in the past would fulfil the requirements for such national decisions, whether Member States would be ready to set up the necessary legislation and infrastructure, and whether negative impacts on the internal market would not outweigh the benefits of national authorisation.

In case main option 2 was to be retained, it would also need to be discussed whether such a national system could also cover joint derogations for sectors, or would be limited to individual derogations.

The future role of the candidate list, including potential information requirements on use and exposure

In options 2 and 3, the current authorisation system would be abandoned and Annex XIV would, after a transition period, become redundant[14]. Nevertheless, the candidate list could remain as a tool to prioritise substances for regulatory action, in particular for restrictions but also for other regulatory action, e.g. under Occupational Safety and Health legislation. In addition, it would remain useful for identifying substances to be tracked under Articles 7(2) and 33, as well as a tool for future instruments that might be developed under the Sustainable Products Initiative (SPI).

Another option to strengthen the usefulness of the candidate list is to introduce requirements to provide more detailed information on uses and exposure patterns for substances on the list, which could then later be used to prioritise substances for further regulatory risk management.

Clarify the interface between REACH and other pieces of EU legislation, including Occupational Safety and Health legislation (OSH)

One option to clarify the interface between REACH and OSH legislation includes the continuation of the current work division, with certain elements to guide preference for one or the other tool. Experience, however, shows that whenever there was strong support for one or the other tool, those guiding elements were not necessarily taken into account. Therefore, also options for changing legislative provisions in REACH and/or OSH legislation should be analysed and discussed in the impact assessment.

Such options could consider e.g. an integrated setting of harmonised risk management measures for the workplace under REACH, for widespread risks related to the use of particularly hazardous substances at the workplace, which require specific control measures, and for which there is a lack of alternatives, and for which there is a need to appropriately monitor emissions in the workplace. Setting such measures under REACH would have the advantage of an integrated consideration of harmonised DNELs for threshold substances (which are a fundamental principle of risk management under REACH and difficult to transfer to other legislation) and OELs. OELs could also become an additional tool to set harmonised practical limits under REACH. Dealing with OELs under REACH should, however, necessarily preserve consultation of social partners,

[14] Substances currently on Annex XIV would need to be covered by future restrictions. Transition measures would need to be discussed.

which due to their experience are essential actors to inform such decisions. Provided that this finds acceptance by the co-legislators, such decisions could take place under comitology, allowing a faster pace of regulation on such workplace related limits. This could e.g. be done by transferring part[15] of the competences to set BOELVs from OSH legislation to REACH through a co-decision act, including provisions on the way social partners would be engaged.

Another possibility facilitating such integrated measures would be tasking OSH legislation to regulate all relevant risks at the workplace under OSH. This would have the advantage of building on the long-established consultation mechanisms under OSH, the closer link to implementation and enforcement by labour inspectors, and the better integration with other parts of worker protection legislation. Furthermore, OSH legislation provides the obligation for employers to replace hazardous chemicals by substances that are less dangerous for workers. The Carcinogens and Mutagens Directives also provides the obligation for employers to use carcinogens and mutagens in closed systems, and if not technically feasible, to minimise the exposure as low a level as technically feasible.

4.2. Restrictions process

The inception impact assessment states that: *'Options include extending the generic risk approach to restrictions to endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs; extending the generic risk approach to products marketed for professional use; and operationalising the concept of essential use in restrictions, including the criteria for granting derogations'*

Simplifications and streamlining

Like for authorisation, specific restrictions under Article 68(1) could benefit from a number of simplifications and streamlining of information requirements for authorities. Initial thoughts include (to be further developed and discussed):

- adjusting the requirements for preparing Annex XV dossiers;
- clarification of the conditions and process of conformity checks;
- reviewing the procedure and timing for the assessment of restriction dossiers in ECHA and COM, including the timing of the consultation period (before or during opinion making);

Introduction of the generic approach to risk management

The most obvious simplification for the restriction process is the planned extension of the generic approach to risk management (restrictions following the procedure of Article 68(2)). For the concerned substances and uses (consumer and professional uses), this starts from the default assumption that risks related to those uses cannot be controlled by the concerned actors, and hence there is no requirement for authorities to prove unacceptable risks, nor is there a requirement to submit a restriction dossier (Annex XV dossier).

The Commission intends to propose the extension of the scope of Article 68(2) to further hazard classes and uses, subject to a comprehensive impact assessment, in line with the announcements of the Chemicals Strategy for Sustainability. The impact assessment will be done through information provided by ECHA and by a study contract. An initial list of concerned substances has been transmitted by ECHA to the Commission and is currently being reviewed. This work will be subject to two workshops, one on the impacted uses

[15] This would necessarily cover only part of the setting of occupational limits, as e.g. REACH does not address chemicals generated unintentionally during processes.

planned for March 2022, and another one to validate the draft final assessment of impacts in June 2022. This will therefore not be discussed in this workshop.

Option of merging authorisations and restrictions

As mentioned in section 3.1 of this paper (option 2), the Commission considers merging the authorisation and restrictions system with the possibility for industry to request joint derogations. For such requests, the burden of proof is on industry, who would be required to submit the necessary information to judge the appropriateness of derogations from restrictions. This could be coupled with further incentives (e.g. financial instruments) to encourage phase-out of derogations and substitution of the concerned substances as rapidly as possible, while keeping the necessary flexibility to deal with intrinsic uncertainties and transition requirements related to the innovation process.

Introducing the essential use concept to restrictions

Like for authorisation, the essential use concept can lead to a simplification and reorientation of the decision making framework on the justification for derogations. This will be assessed separately and is not part of the discussion of this workshop.

Strengthening the role of the Forum to assess enforceability of restrictions

In order to improve the enforceability of REACH restrictions, one option to be evaluated is to give the Forum the task to issue an opinion on enforceability.

Improving feasibility of REACH restrictions for SMEs

An option to encourage systematic checks of specific impacts for SMEs is to require a specific section on SME impacts in each restriction proposal.

5. QUESTIONS TO BE DISCUSSED AT THE WORKSHOP

At the workshop, participants will be assigned to one of four 'world café' tables, which will discuss in total eight questions - four in the morning and four in the afternoon. For each of the questions, the table has 30 minutes to discuss, and all participants should be able to speak. It will be essential that participants come well-prepared and provide clear and synthetic messages. There will be a moderator and a rapporteur at each table. For participants in Slovenia, the world café tables will take place physically, for remote participants the tables will be virtual. None of those tables will be recorded or web streamed, but the summary by the rapporteur will be presented in the closing session.

5.1. Morning session:

- *Problem analysis and objectives*

What is the view on the Commission's initial analysis of underlying drivers, in particular the analysis of the implementation of the current REACH authorisation and restriction processes and their achievements, problems and deficiencies? Are there missing elements?

- *Option 1: Elements for simplification under the current authorisation and restriction system*

What is the view on the Commission's initial collection of elements for simplification of the current authorisation and restriction systems? Are important elements missing? To what extent would addressing those elements be sufficient to remedy the observed problems with authorisation and restriction?

The intention is not to go through the identified elements one-by-one, but rather to look at the overall question on what could be done to improve the existing authorisation and restriction systems. Detailed comments are welcome in writing to GROW-ENV-REACH-Revision@ec.europa.eu.

- *Option 2: Merging authorisation and restriction*

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

- *Option 3: Removing the authorisation title from REACH completely or partially; role of restrictions, role of the candidate list; notification obligations for uses after SVHC identification*

What is the initial view on the option of removing the authorisation system entirely? Should the candidate list be maintained, if so why? What could be the future role of the candidate list and what obligations should be attached to it?

5.1. Afternoon session:

- *Level of ambition, advantages/disadvantages of options 1, 2, 3*

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

- *National authorisations, international level playing field and export bans*

  What are the views of participants on national authorisations as an appropriate tool to reduce the burden on ECHA and the Commission and to better take into account local conditions and preferences? What about internal market impacts, resource needs etc.?

  What other ideas than those outlined in this paper do participants have to create a better level playing field, in particular for activities where regulated substances are not present in the final product?

  Are there considerations to be taken into account on the planned bans for exporting substances that are restricted in the EU?

- *Interface REACH-other EU legislation*

  Would a stronger integration of regulating work place related risks create value added compared to the current situation? What aspects are to be considered? Should a stronger integration imply transfers of legislative tasks (i.e. certain BOELVs from OSH to REACH, or all worker protection measures from REACH to OSH) make sense? Which route should be preferred? What are the elements that an impact assessment on such options should be considered? Are there additional options? Should there be a stronger integration of measures with permitting under the Industrial Emissions Directive?

Are there interfaces with other EU legislation which should be assessed as a priority?

- *Innovation and how to support substitution; improving enforceability and impact on SMEs*

  What is the view on the use of financial instruments to incentivise substitution at EU level? How could such financial instruments be designed? Are there any other ideas how to promote innovation and substitution under REACH? What is the view on giving the Forum a similar role as RAC and SEAC? What measures can be taken to accommodate specific constraints of SMEs?