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Directions for the REACH revision – CARACAL 54

Comments by ClientEarth (revised)

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1. Introduction and procedural remarks

The Commission presented the "*Key elements, state of play*" for the REACH Revision currently under preparation to Member States and Stakeholders at CARACAL-54 on 3 April 2025. ClientEarth thanks the Commission for this opportunity to provide feedback by 25 April.

Revising REACH is a highly significant policy initiative which will affect every living being and all ecosystems throughout the Union as well as hundreds of thousands of companies. This should set a high bar for the impact assessment justifying every element of the revision. Referring to the presented timetable for the revision, by August the Commission intends to complete the update of the existing impact assessment for the REACH proposal(s) which are then set to by published by Q4 of 2025. The Commission intends to make this commenting period a last opportunity to hear from stakeholders.

ClientEarth notes that **the Commission's presentations at CARACAL-54 of the options considered for the revision often significantly lack clarity, making it impossible for stakeholders to comprehend their potential impact**. This, next to the short commenting period of 3 weeks, limits stakeholders' ability to provide meaningful feedback. These deficits **raise serious doubts whether this procedure meets the rules of the Commission's very own Better Regulation guidelines**, which define "*minimum standards that apply to all consultations*", including sufficient time for participation and "*clarity – all consultation documents should be clear and concise, and include all necessary information to facilitate responses*".[1]

From a civil society perspective, it is particularly concerning that the **impact of the revision on the primary objective of REACH to ensure a high level of protection, but also on EU competitiveness of innovative companies developing alternative solutions for harmful substances, is not at all clear**.

Given the significance of the REACH revision the Commission has to take all the time it needs to collect relevant evidence for the impact assessment[2] – notably for the policy options designed to simplify REACH and which have not already been scrutinised in the existing impact assessment. **The current simplification push, shaping the political context, is not an objective reason to rush things and cannot alone justify deviations from the Better Regulation guidelines**.

The following sections provide comments on the considerations outlined by the Commission at CARACAL-54. This entails recommendations to refine options, so they increase the level of protection of REACH while not missing out on simplification potentials. More details on ClientEarth's recommendations to future proof REACH can be found in the comments submitted following CARACAL-53 as well as in previous contributions.[3]

ClientEarth supports many options considered, including the introduction of new tools in the context of Registration to enforce the 'no data no market' rule (Section 2). By contrast, the plans to revise the Authorisation regime, linked with new roles for the Candidate List and Analysis of Risk Management Options (RMOA), are particularly concerning as they may fortify existing bottlenecks for regulatory controls, while violating both the objective of REACH to phase-out SVHCs and procedural rights of authorities (Sections 6 and 7).

[1] Better Regulation Guidelines, SWD(2021) 305, p. 15.
[2] Better Regulation Guidelines, SWD(2021) 305, p. 4, stating "*the depth of analysis should reflect the significance of the impacts or effects that a given initiative or intervention*".
[3] ClientEarth (2023), Demands #1-6 for REACH reform.

2. Registration

ClientEarth agrees with the Commission that to ensure a high level of protection, while also facilitating competitiveness and innovation, **it is not anymore justified to grant privileged access to the market for substances regulated under the regimes pre-dating REACH**. Lighter registration requirements for substances notified under the previous chemical legislation should therefore be removed, and an update required to meet all requirements in accordance with their volume be put in place. Provisions for phase-in substances should be deleted.

Besides, we agree with considerations to require registrants of dossiers with only physicochemical information to update to full Annex VII requirements. Furthermore, ClientEarth strongly **supports** the considered **clarification that identification of a substance as SVHC triggers the requirement to update the registration dossier. In addition, the entry in the Registry of Intentions of a new restriction initiative targeting a substance should have the same triggering effect.**

2.1 Validity of registrations to reenforce dossier updates

ClientEarth agrees that a validation mechanism as considered by the Commission can be a good instrument to tackle the issue of abandoned zombie dossiers skewing ECHA's database of registered substances. As presented by the Commission, the burden of revalidation as such would be minimal.

In addition, much of the data provided by registrants is likely outdated, with only 10% of registrations updated each year.[4] The validation mechanism incentivises registrants to update their dossiers an update according to Article 22 REACH as it would re-set the validation clock. Conversely, to reenforce these incentives, **a validation invoked by a registrant should trigger the obligation of this registrant to assess update needs** pursuant to the existing obligations under Article 22(1) and Commission Implementing Regulation 2020/1435. Any update or omission of an update **should be made subject to the completeness check** under Article 22(3) or should trigger the ad-hoc completeness check to be established (see below).

To further foster incentives, for each dossier, **the validation clock should be clearly visible so potential customers, civil society and investors can see when the dossier has been last updated.**

To truly enhance confidence in the registration data, the 10-year time frame envisaged seems too long. The Commission should thus consider to significantly reduce this frame (to e.g. 5 years) or at least to create a mechanism that would, on the one hand, mandate the Commission to assess if the validation scheme as suggested sufficiently contributes to its intended goals and, on the other, allow the Commission to adopt an implementing act changing the scheme and to **introduce a generic update requirement (e.g. every two years)**.

2.2 Long overdue ad hoc completeness check

ClientEarth strongly supports the introduction of the ad hoc completeness check which could level the playing field between newer dossiers and legacy dossiers submitted in the early days of REACH when no meaningful completeness check has been in place. **ECHA should be given the mandate to perform ad hoc checks at any time, without limitations.**

[4] ECHA 2021, report on the Operation of REACH and CLP, p. 41.

2.3 Revocation of registration number

As regards persistently incompliant dossiers, the application of the "no data, no market" principle by means of the withdrawal of the registration number is the appropriate administrative measure. REACH however does not mention this remedy explicitly. **ClientEarth therefore strongly supports the Commission's considerations to introducing an option for ECHA to revoke the registration number.**

2.4 Modernise information requirements

Work on the modernisation of information requirements subject to REACH Annexes has already begun. As regards EDCs, to meet the CSS ambition to "*ensure that sufficient and appropriate information is made available to authorities to allow the identification of endocrine disruptors*"[5], the proposals shared by the Commission leave room for improvement. **We trust that the Commission will revise the proposals taking into account comments received by Member States and environment and health NGOs**.

2.5 Modernise the chemical safety assessment, including MAF

To further reflect scientific progress, REACH should explicitly require industry to assess PMT, vPvM and EDC properties and related risks in the chemical safety assessment (CSA) – as is considered by the Commission. In addition, it should be clarified that **differences in biological sex and age** and their implications for variation in potential effects must be taken into account in all steps of the CSA.

To modernize while also simplifying the CSA, a presumption of risk should apply in situations where a substance on its own, as a constituent of other substances, in a mixture or in an article meets the criteria for classification as CMR, EDC, STOT, PBT, vPvB, PMT or vPvM.

Furthermore, humans and the environment are constantly exposed to multiple substances. **There is ample scientific evidence that cocktail effects and multi-exposures of chemicals cause adverse effects to human health and the environment** – yet REACH does not oblige companies to assess and control risks from combined exposure. With a view to adapting REACH to scientific progress, ClientEarth strongly supports to plug this legal gap. Compared to obliging companies to identify and scrutinise each actual co-exposure for any given substance, **introducing a generic mixture assessment factor (MAF) is a practical and efficient approach to address such risks**. To ensure a high level of protection, this factor should be set at a value of at least 100. At the minimum, the Commission should implement the MAF concept already outlined at CARACAL-48 (28 March 2023).

2.6 Polymers

Polymers are exempt from REACH registration requirements but meanwhile studies have shown that the societal benefits of registering at least a subset of polymers outweigh the costs.[6] ClientEarth therefore strongly supports the Commission's considerations to introduce a tiered regulatory approach to

[5] COM(2020) 667, p. 11.
[6] Wood and PFA-Brussels (2020). Scientific and technical support for the development of criteria to identify and group polymers for registration/evaluation under REACH and their impact assessment.

polymers, consisting of a notification step for all polymers to identify the subset of polymers that require registration in a second step.

2.7 What else is missing

Information on uses and alternatives. A main failure of REACH is that the registration dossiers lack data on chemical uses and available alternatives.[7] To fill data gaps, a new mechanism is needed to ensure the notification of key information from downstream users to public authorities, backed up with strong incentives for completeness and accuracy (see below). This obligation should **apply to all substances on the Candidate List** or that are subject to a new entry on the **Registry of Intention for restrictions**. Downstream users should be obliged to report to the Agency for any use of any substance, the function(s) of substances in mixtures and articles, mixture and article category(s) with sub-category(s) by application, process category(s), with sub-category(s) by application, substitution plans including efforts done and planned, and potential alternatives etc.[8]

Strong incentives for compliance. We propose that companies in breach of the existing or new information obligations for registrants and downstream users are excluded from the right to apply for authorisation and cannot benefit from derogations under the authorisation and restriction schemes.

Transparency as driver. In the current simplification and competitiveness context, new avenues to improve the implementation of REACH and compliance need to be explored. **Transparency should be enhanced for potential customers, investors and civil society at large to better enable market developments toward compliant, safer and more sustainable chemistry.** To that effect, we suggest refining Articles 118 and 119 and expand ECHA's mandate to grant access to more granular tonnage data, the identify of registrants and their parent companies, information from enforcement of REACH etc.[9]

3. Evaluation

ClientEarth supports the Commission's considerations to increasing efficiency and impact of the compliance check as well as to simplify, increase efficiency and impact of substance evaluation. Notably, we endorse the removal of the fixed percentage of compliance checks in the legal text to the extent that achieving **full compliance should be the ambition level**.

Information requests following substance evaluation may only be addressed to registrants. Learning from good practices in competition law,[10] **we propose to create a new duty for any actor in the supply chain of a substance, mixture or article containing a substance, as well as their competitors and association of actors to respond to requests from ECHA and competent authorities**. Those requests should not be limited in scope, and address, for example properties, use, function, exposure, potential alternatives.

[7] Impact Assessment submitted to the Regulatory Scrutiny Board (2023), 9. See also ECHA 2021, report on the Operation of REACH and CLP, pp. 66 et seq; ECHA 2021, report on the Operation of REACH and CLP, p. 8.
[8] For details see Demand #2 for REACH reform: No data, no market - from slogan to reality | ClientEarth (2023).
[9] For details see Demand #2 for REACH reform: No data, no market - from slogan to reality | ClientEarth (2023).
[10] In the context of competition law, authorities are equipped with similar powers, see Articles 18–21 of Regulation (EC) 1/2003.

4. Nanomaterials

ClientEarth supports the Commission's goal of improving requirements relevant for nanomaterials as well as related considerations to clarify reporting requirements for downstream uses and to clarify the scope of compliance check.

Considerations to "*Clarify information requirements for registrants*" (and downstream users) to "*facilitate implementation of concepts of nanoform and set of similar nanoforms*" should take into account fundamental concerns raised inter alia by Germany with the concept 'set of similar nanoforms' and its frequent misuse by industry to avoid data provision.[11] In addition, **REACH needs to define vague concepts key to the assessment of nanomaterials**, such as 'poorly soluble', 'high insolubility' and low/high dissolution, and further define environmental risk assessment of these substances.[12]

As regards the definition of nanomaterials, to avoid lowering the level of protection**, the Commission should adapt the text of the 2022 Commission Recommendation for the purpose of REACH**, following recommendations set forth inter alia by France.[13]

5. Supply chain communication

ClientEarth supports considerations to provide for a harmonised electronic format, to improve usability and to improve the extended SDS.

As regards the digitalisation of supply chain communication on SVHCs in articles, ClientEarth agrees with the Commission that this information is highly relevant not only to ensure safety but also to track substances of concern to enable a more circular economy. To generate and communicate this information, effective information flows along the supply chains are key. To this end, Article 33(1) introduces a horizontal requirement for article supply chains of all sectors to report presence of SVHCs. Yet, the Commission, in its 2020 review observed weak implementation of Article 33 REACH.[14] ClientEarth supports the Commission's considerations to interlink obligations under Article 33 with obligations in connection with Digital Product Passports to the extent it facilitates full implementation of the legal requirements while avoiding double reporting.

However, **these considerations do not address the lack of clarity of the Article 33(1) obligations, a major cause[15] for the poor implementation**. To facilitate the information flow, ClientEarth therefore proposes to clarify the obligations under Article 33(1), including the clarification that the relevant SVHC information must be available upfront before purchasing so that customers can avoid SVHCs in their products, and the clarification that after a Candidate List update the article supplier has to update its SVHC report to the customers.[16]

[11] German Federal Office for Chemicals (2025). DE Paper: Assessment of the enforceability of the rules for nanomaterials in REACH – review five years after entry into force, submitted to CARACAL-54.
[12] Schwirn, K., Voelker, D., Galert, W., Quik, J. and Tietjen, L. (2020), Environmental Risk Assessment of Nanomaterials in the Light of New Obligations Under the REACH Regulation: Which Challenges Remain and How to Approach Them?. Integr Environ Assess Manag, 16: 706-717.
[13] Anses (2022) Scientific and technical support NOTE on "preparing a proposal for an updated definition of the term 'nanomaterial' based on Recommendation 2011/696/EU".
[14] SWD(2020) 247 final.
[15] See the UBA report Advancing REACH: Substances in Articles (2020).
[16] For details see Demand #2 for REACH reform: No data, no market - from slogan to reality | ClientEarth (2023).

As for the consumer information, also the design of the 'right to know' on SVHCs in articles is flawed. **To turn this mere right to ask into a strong right to know, Article 33(2) needs to be expanded to the effect that suppliers are required to answer requests in any case and that the available 45-day period to give the answer is significantly reduced - toward the immediate automated provision of the information**.

6. Risk Management (overarching)

6.1 Upfront analysis of risk management options (RMOA)

The Commission considers introducing as part of the REACH revision the Analysis of Risk Management Options (RMOA) as a mandatory upfront assessment step before specific regulatory routes are formally initiated. As for the available options, the Commission is considering a pool which includes, besides REACH Authorisation and Restriction, also instruments under "OSH, IED etc".

Already today, authorities perform RMOA (see section 6.1.1) and ClientEarth supports that for each chemical risk authorities pick the best regulatory instrument. But **while the Commission intends to simplify REACH by making this upfront step mandatory, the effects would be exactly the opposite**.

Notably, mandatory RMOA would limit authorities' ability to directly pick the instrument deemed necessary and proportionate, for an authority may already possess all evidence needed. In such a case **RMOA would at least delay action as it usually takes more than one and a half years,[17] requiring – i.e. wasting – significant resources of all authorities involved.** In addition, as regards regulatory control of SVHCs, RMOA **structurally violates the phase-out goal in Article 55 REACH** (Section 6.1.3).

Furthermore, the impact of RMOA could be more devastating if its final output were to be a binding decision rather than mere opinion or recommendation. This would create new red tape and violate authorities' procedural rights (see below 6.1.2). Additionally, a binding decision would expose authorities to the risk of industry litigation. Legal challenges of RMOA decisions may not prevent authorities from proceeding with the selected regulatory choice. However, **the prospect of being challenged in court by industry may have an intimidating effect on authorities and consequently lower their ambition.**

Finally, the mere outline of this 'concept' raises fundamental legal concerns: if RMOA were to be legally implemented in REACH **it does not seem feasible to take 'within' REACH a binding decision that invokes the implementation of measures under laws *other* than REACH** – at least not without first amending such laws to that effect. These considerations alone indicate that RMOA should remain outside of the REACH legal framework.

[17] EEB (2022), The Need For Speed, p. 31 concludes, based on an assessment of 349 RMOAs/ARNs that "*the fastest ARN conclusion took less than a month. The median duration was one year and eight months and the longest was ten years and 11 months*".

We urge the Commission to not make RMOA mandatory and thereby introducing new bottlenecks s slowing down progress on the regulation of chemical risks. Instead, we ask the Commission to do the following:

- Ensure that REACH generates all the information needed to make regulatory choices, by introducing new mechanisms and subsequent bold implementation.
- Further develop voluntary RMOA by streamlining the interplay of OSOA Expert Group, RiME+, ARN and RMOA.
- Do not limit the scope of RMOA to SVHCs but rather target chemicals which are largely ignored, e.g. self-classified chemicals, pool of unassigned chemicals in the chemical universe and (new) notifications of uses implying exposure.
- Enhance transparency and allow feedback from stakeholders during voluntary RMOA, including from Civil Society and developers of alternatives to hazardous chemicals.

6.1.1 Adding more RMOA does not add value

The added value of the revised RMOA compared to the current system is not clear. First of all, the idea of analysing available options before initiating a procedure is not new. Rather, in the context of Restrictions there already is a duty for dossier submitters under Annex XV to establish that "*restriction is the most appropriate Community wide measure*", which must include an assessment of all possible regulatory routes and an analysis of their relevance to address the risk at stake. Additionally, there is a lot of informal RMOA activity. By end of 2023, ECHA had looked into 240 groups of substances, covering in total approximately 6.300 substances, as part of the Agency's Assessment of Regulatory Needs (ARN).[18] This is in addition to RMOAs voluntarily performed by Member States. Additionally, there exists an Risk Management and Evaluation (RiME+) platform[19] and an Expert Group on One Substance, One Assessment (OSOA)[20] where MSCAs, Commission, ECHA and, in the case of OSOA additional agencies, discuss regulatory options for a given situation.

This all is evidence that there is already a lot of activity in the context of RMOA. The impact of these activities however appears to be very low. For example, an assessment of 349 RMOAs or ARNs performed between 2011 and 2022 concluded that, by the time of publication, only three chemicals have been subjected to strict control measures (two restrictions and one SVHC inclusion in Annex XIV).[21] This assessment moreover found the median duration of ARN/RMOA to be one year and eight months.[22]

The Commission is looking for "*Upfront analysis and discussion of regulatory options*" and "*Better up front prioritisation and design of restriction proposals to avoid overloads and delays in the restriction*

[18] ECHA, IRS Annual report 2023, p. 13.
[19] See RiME+ (Risk Management and Evaluation) platform - ECHA according to which the platform "*facilitates voluntary coordination and discussion on activities related to the implementation of the integrated regulatory strategy, covering the different REACH/CLP processe*s".
[20] See Register of Commission expert groups and other similar entities, according to which the group is tasked with, among other things, "*the coordination and discussion of initiatives on safety assessments of chemicals across chemical legislation, with particular focus on substances and group of substances that are in the scope of several pieces of chemical legislation or initiatives*".
[21] EEB, The Need For Speed, published 11 July 2022, p. 33.
[22] EEB (2022), The Need For Speed, p. 31.

process". All this can already be achieved using the existing mechanisms and fora outlined above, which the Commission may wish still to improve (e.g. streamline, enhance transparency, stakeholder involvement).

6.1.2 RMOA may foster the violation of authorities' procedural rights

When it comes to regulating chemical risks, **REACH establishes obligations and procedural rights, both for the Commission and for the Member States**. Besides the Commission, Member States have the legal mandate to make proposals for SVHC identifications and for restrictions (Article 69). Risk management is thus a shared responsibility in REACH. Member States' rights to initiative have to be respected. Yet **there are serious concerns that RMOA could provide a platform for the Commission and industry to lower the ambition of Member States. To exclude this risk, Member States should maintain their unrestricted rights to initiative – RMOA therefore must not become obligatory.**

6.1.3 RMOA would violate the core objective of REACH

Additionally, mandatory RMOA would violate authorities' duties, as discretion in choosing the right instrument de lege lata has its limits.

Notably, **REACH Article 55 aims for the phase-out of all substances of very high concern. This phase-out goal not only specifies the REACH primary objective to ensure a high level of protection for the case of SVHCs. Article 55 is moreover the only verifiable commitment in REACH to act against hazardous chemicals, thereby creating a minimum level of accountability**. The regulation establishes the Authorisation regime to achieve this phase-out. In other words, the default measure for regulating SVHCs is subjecting them to Authorisation, which creates a ban of all uses, unless exempted from Annex XIV or to the extent that an authorisation has been granted.

The idea behind RMOA however is to <u>not</u> by default send SVHCs to Annex XIV. Instead, RMOA might identify as most appropriate tool to regulate SVHCs a REACH restriction, which, depending on the design, can be considered a functional equivalent to Annex XIV. But the Commission stresses that RMOA may also select measures under IED, OSH "*etc.*". Accordingly, SVHCs may end up in mere emission control. **Emission control is not foreseen in REACH for the legal category of SVHCs**. Rather, **any measure that would not ensure the phase-out for SVHCs would violate the core objective of REACH.**

6.2 Role of the CL

The Commission considers a "[c]*hanged role of candidate list: tool to prioritise regulatory action in general, instead of being first step to authorisation only*", thereby raising several concerns.

6.2.1 Damaging the anticipatory effect

In the current system, identification as SVHC and subsequent inclusion in the Candidate List (CL) creates a strong anticipatory effect: as companies want to avoid reporting obligations (under Article 33 REACH) or an authorisation requirement with the risk of market access not being granted, many are proactively looking for substitutes. Referring to assessments done by ECHA, the REACH Impact Assessment submitted to the RSB acknowledges that the "*inclusion of a substance in the Candidate List*

and in Annex XIV are, besides REACH restrictions, the most significant triggers for companies to start their substitution activities".[23]

It is not entirely clear which scope the Commission has in mind when referring to "*regulatory action in general".* We assume all actions subject to the Commission's idea of RMOA would generally be considered available for CL substances. This would imply that CL substances could eventually end up regulated under IED and OSH, both regulatory choices industry usually prefers over the stricter REACH instruments Authorisation and Restriction. It is thus highly likely that, **after CL inclusion of a substance, manufacturers and users would put their attention and resources into advocacy in favour of 'softer' regulatory measures (e.g. under the IED or OSH)** – instead of initiating substitution. This option would therefore severely damage the current anticipatory effect and thus weaken the impact in terms of level of protection and innovation push.

6.2.2 Substances in scope

It is not clear which chemicals / groups of chemicals the Commission intends to submit to the revised CL.

However, the Commission appears to be considering having the CL as the entry point for RMOA. RMOA in turn is intended to become the default upstream process to identify for a given CL substance the best regulatory route, including, but not limited to, REACH Authorisation and Restriction. We assume this is the setting the Commission has in mind. Starting from there, **one can think of different scenarios for the composition of the revised CL – all of which are creating conflicts with the existing regulatory mechanism under REACH**.

For instance, the CL could remain reserved for SVHCs. **This would practically limit the scope of Restriction to SVHCs**, thus severely undermining the legal procedures set out in Title VIII **that de lege lata have no limits as to the substances potentially falling in scope** of a restriction. This effect may be eased, at least to some extent, by expanding the criteria of Article 57 to cover additional hazards (Section 7.4).

The CL could also be opened to other substances, alongside SVHCs. However, also in this scenario, repurposing the CL would **require changing the current wording of Article 59(1)** introducing "*a candidate list* [of SVHCs] *for eventual inclusion in Annex XIV*". This alone **amounts to weakening the phase-out goal for SVHCs under Article 55** (see already Section 6.1.2).

RMOA must not limit the scope of Title VIII, neither must it interfere with the fragile architecture of Title VII of REACH. To maintain the effectiveness of REACH Authorisation, the original CL purpose should be retained. **The role of RMOA could be taking care of those substances that have not already affected regulators' attention but for example can be found in the "unassigned" pool of the chemical universe or are (self-) classified.**

6.3 More information earlier in the process

The Commission states one motivation for the revision is that "*[i]nformation on use, exposure and alternatives becomes available too late in the authorisation and restriction process*". Accordingly, in the Commission's view "*earlier information*" or "*[u]pfront information on use, exposure and alternatives*" can simplify by allowing to better target regulatory action. ClientEarth fully supports this thinking.

[23] Impact Assessment submitted to the Regulatory Scrutiny Board, Annexes, 479.

It remains unclear which mechanism(s) the Commission is considering introducing as part of the revision. However, the purpose of the revision should be to make up for the shortcomings of the REACH registration requirements, which have failed to generate relevant use and exposure information based on interactions both downstream and upstream the supply chains. The **new mechanism(s) should thus at least partly apply to all downstream users of certain substances, such as SVHCs**. Only such broad application would plug the registration gap and ensure that at least basic information gets available to prioritize risk management options *before* control measures such as Annex XIV or Restriction are initiated. Above (Section 2.7) we make a proposal on how to design the obligation in a way that all information relevant for regulatory decision-making becomes available upfront.

Building on this broad obligation, additionally **a targeted information requirement would add value**. The requirement would be targeted because authorities could invoke it only in relation to specified use cases. Should authorities choose to trigger the mechanism, basic administrative principles such as proportionality would apply. Apart from proportionality considerations, there should not be any limit as to the scope of a targeted information request. The mechanism suggested in the context of Evaluation (Section 3) and inspired by competition law would be one way of designing this new instrument.

But if the Commission nevertheless intends to limit the scope, (self) classification of a substance should suffice for authorities to be legally entitled to make targeted requests.

6.4 Essential use

The Commission is still considering the "*simplification potential of the essential use concept*" in the context of Restriction and Authorisation. ClientEarth would like to draw the Commission's attention to the comments submitted following CARACAL-53 with recommendations for the implementation of the Essential Use concept.

7. Authorisation

The Commission's presentations at CARACAL are reassuring that removing the Authorisation regime is not considered. ClientEarth agrees that removing legal hurdles to enhance the interplay of Authorisation and Restriction can improve implementation of REACH (Section 7.1). Any flexibility gains would however be destroyed by the constraining effects of RMOA and misguided refined prioritisation criteria (Section 7.3). Meanwhile the obvious simplification option to expand the Article 57 criteria is overlooked (Section 7.4).

7.1 More flexibility and clarifications can improve implementation

ClientEarth supports the Commission's considerations to remove Article 58(5) and (6) to provide for more flexibility to restrict certain uses of a substance listed in Annex XIV. Better combining both instruments could yield higher protective effects compared to using just one option or the other. At the same time, it could reduce the authorisation workload by sending only those uses to authorisation where data (e.g. on alternatives) is missing.

Besides, the Commission considers clarifications on the "*key elements for applications for authorisation (AoA, Substitution plans, etc)*". The Commission committed to reduce the need of individual applications for authorisation. In addition, there is undoubtedly an issue with the quality of the AfAs – one that has too

many times failed to be rigorously sanctioned by the Commission and has led to the undue granting of authorisations at a final stage. ClientEarth agrees that, to address both shortcomings, some key provisions in Title VII could be clarified. As acknowledged by the Commission, clarifications of key concepts under Article 62(4) (analysis of the alternatives, suitable alternative) are needed to facilitate that only robust AfAs are submitted. In addition, to reduce the need for individual AfAs, upstream applications still bear great potential. To that effect, the conditions pursuant to Article 62(2) under which upstream applications can be made (e.g. homogenous exposure scenarios, consistency of substitution timeline) should be clarified, taking into account the considerations of the European Court of Justice.[24] If done right, such clarifications would facilitate the Agency's conformity check under Article 64(3) to ensure that only robust AfAs enter the opinion-making stage.

Clarification alone however will not suffice to fully overcome shortcomings in implementation. Rather, **it is of the utmost importance that the Commission shows more ambition in the implementation of the Authorisation regime, having the phase-out goal of Article 55 in mind**: **authorisation should not be granted** if applicants fail to provide sufficiently credible information about either the lack of alternative (which oftentimes is misleading, because in fact substitution should have started a while ago and companies just wait for the last minute to start R&D) or their substitution plan.

7.2 Period of grace for rejections

Today, the rejection of an application is politically sensitive because of its immediate impact. Introducing the possibility, as considered by the Commission, to define a "*transitional period to cease the use in case of refusal of authorisation*" could reduce pressure**. The legal text should define a maximum grace period of 12 months**.

7.3 Considered changes to the prioritisation criteria are misguided

The Commission considers changing the prioritisation criteria in Article 58(3). ClientEarth agrees that adding a substance's "*potential to be used as alternative for substances already in Annex XIV*" provides a useful addition to the current system because it helps to avoid regrettable substitutions.

With the other suggested criteria, however, the Commission aims at *"[l]imiting applicant by applicant authorisation*". Already today Article 58(3) states that, when including substances in Annex XIV, the Commission "*shall also take account of the Agency's capacity to handle applications in the time provided for*". Yet, **to properly account for the likely number of applications is not possible given the severe lack of use information under the current regime**. This is why the priority should be to get better hold of the use data (see Section 6.3).

To limit the number of AfAs, the measures considered providing more flexibility and clarifications are pivotal (see above). **Changing the Article 58(3) criteria could, however, have the opposite effect and limit the Commission's flexibility when it comes to improved interplay of Authorisation and Restriction**. For example, by considering to prioritize substances that are "*not ultimately incorporated in articles*" the Commission is creating red tape. First of all, implementing this would, again, depend on data on the presence of a substance in articles – which is usually not available. In addition, strictly speaking this criterion aims to remove the option to tackle serious risk from the use of substance to produce an article with Authorisation, without considering if a restriction under Article 68(2) could be invoked. In the

[24] Case T-837/16, Kingdom of Sweden v European Commission; appeal Case C-389/15 P, European Commission v Kingdom of Sweden; Case C-144/21, European Commission v European Parliament.

end, authorities may be forced to handle substances in articles under the ordinary restriction regime by default even if Authorisation may be the preferred option to take swift action ensuring a high level of protection.

Finally, many details remain unclear. For instance, it is not clear whether the idea is to keep hazard prioritization criteria in place, whereas **tackling persistent chemicals, i.e. PBT, vPvB and potentially also PMT and vPvM, should remain a top priority for regulators**. Besides, it is not clear whether the considered criteria should apply as alternatives, as is currently the case, or cumulatively. If the idea is to apply them cumulatively, this would disproportionally raise the bar for placing a substance on Annex XIV.

7.4 What else is missing

To improve authorities' flexibility when considering regulatory instruments, the Commission should aim to make REACH Authorisation more viable. **To reduce the administrative burden of Annex XIV listing, the identification of SVHCs should be simplified by adding new criteria to Article 57**: The procedural shortcut available for CMRs, where harmonized classification under CLP may unlock the SVHC status, should be expanded to additional hazard classes. Following commitments under the CSS, the same mechanism should apply to EDCs, PMT and vPvM.

8. Restriction

8.1 Restriction dossier design for the submitters to decide

With a view to improving "*design of restriction proposals to avoid overloads and delays in the restriction process*" the Commission considers taking into account "*authorities' capacity and legal deadlines when preparing restrictions (e.g. splitting proposals where too big)*".

First of all, REACH ascribes to the dossier submitters some level of discretion when they intend to regulate chemical risks while at the same time Article 69 and Annex XV in conjunction with Annex I define strict criteria limiting this discretion. The Commission's considerations lack clarity, but it appears they try to draw lessons from the uPFAS restriction dossier – the processing of which creates challenges for authorities. Note that there are mainly three drivers for these challenges, i.e.

- the comprehensive scope of the dossier,
- the fact that REACH data requirements were unfit to collect all data needed from industry to design the dossier and, linked with that,
- the lack of cooperation, including the sharing of data, by many industry stakeholders early in the process vs the extensive volume of information submitted to the public consultation by these same actors which led to a hardly manageable data overload.

To cater for the concern that "*too big*" dossiers cannot be feasible to handle in the legally set timeframes, **the REACH revision could introduce the possibility to extent the legal deadlines for opinion-making and decision-making, provided specific criteria are met** (e.g. scopes of chemicals and uses covered by a dossier).

Besides, the Commission should introduce improved requirements that ensure early access to information on polymers, on uses and on available alternatives. This would allow a more targeted

framing of restrictions, less reliance on the sharing of information by third parties, and would avoid an avalanche of new and relevant data in the consultations (see sections 2.6 and 2.7). **Improved data requirements would appreciate that chemical risks and industry's unwillingness to share data about it are the source of the problem, and not the ambition of authorities to tackle such risks.**

RMOA can be utilized to exchange on restrictions proposals and splitting options at the stage of preparation, i.e. *before* the dossier is formally submitted.

Given the delicate separation of powers in REACH risk management (see Section 6.1.3), **the Commission should never be entitled to split at the opinion-making stage a dossier submitted by a Member State**.

The solution to addressing uncertainties or information gaps in a broad restriction should not be to reduce the level of ambition of the restriction that was originally thought as the only effective, and appropriate measure to deal with an uncontrollable EU wide risk, e.g. by narrowing down its scope or exempting wide categories of uses. We would like to emphasise that the precautionary principle (found in Article 1 of the regulation) remains and should serve as a guiding principle to deal with the unacceptable risk posed by harmful chemical families like PFAS or bisphenols.

8.2 Forum advice must not impede regulation

The Commission considers integrating "*Forum advice into restriction chapter (formerly only in Forum tasks)*". Already today, Annex XV requires any restriction to be "*implementable, enforceable and manageable*". Building on that, Article 77(4)(h) tasks the Forum with "*examining proposals for restrictions with a view to advising on enforceability*". The Forum provided its advice on most recent restrictions discussed by the ECHA committees.

Given this existing mechanism, the purpose and extent of the considered option are not clear. The Commission is well aware that while some companies may actually neglect compliance efforts regarding a chemical restriction if it is not enforceable, lack of enforceability does not make the chemical risk subject to the restriction go away.

The adoption of a restriction is expected to create market incentives to develop laboratory capacities, methods and standards, if gaps exist. Additional support to mitigate such gaps (e.g. standardisation mandate, research) would be helpful. Given the primary objective to ensure a high level of protection, though, **the legal text should make clear that lack of enforceability can never prevent, limit or delay the adoption of a restriction.**

Enforceability issues should however continue to be highlighted as an important consideration and support the definition of the conditions of a restriction – as it has been done by the Forum up to now. For that reason, we do not see the need for a change in the Forum advice status nor its role.

8.3 Legal substitution push is feasible

The Commission considers taking additional "*action to support substitution (substitution pathways, substitution centres, innovation, safe and sustainable by design)*". According to companies, regulation is the main reason for substitution efforts. Therefore, **it is paramount to maintain this key driver by defining regulatory phase-out dates by which use of a substance would no longer be legal**. These legal deadlines can be stipulated both under REACH Authorisation and Restriction.

In the context of Restriction, **REACH already provides the instruments needed to ensure that industry actively works towards substitution to implement the substitution plan and that a phase-out date does not unnecessarily prolong substitution processes**. A substitution plan would already be defined in the context of the Annex XV dossier. It can cover several uses, depending on consistency of the substitution activities required. The Annex XVII entry could then stipulate the implementation of the plan and, for example, comprise the following elements:

a. Milestones for research & development activities.

b. Reporting obligations to show compliance with a, including specification of the related types of verifiable evidence to be submitted to ECHA. ECHA would make the data received available to Member States to enable enforcement.

c. Depending on the length of the transitional period / substitution planning, the Commission could be required to perform a (e.g. mid-term) review of whether the concerned uses still meet the conditions for the derogation, i.e. alternatives are not yet available

All this could be done by implementing REACH. Changes to the legal text would not be needed.

8.4 Bold extension of generic risk management approach needed

The Commission considers to extent the generic risk management approach (GRA) for substances with certain hazard classes in consumer uses as "*simplification element*" for the REACH revision. This acknowledges the adapted burden proof for authorities under Article 68(2) to tackle situations where unacceptable risk is presumed.

To ensure a high level of protection, in line with the commitments made under the Chemicals Strategy for Sustainability (CSS), and lower administrative burden ClientEarth recommend the following changes:

- The hazard classes need to be extended at least to EDCs, PBT/vPvB and PMT/vPvM substances where these meet the CLP criteria or are on the REACH Candidate List.
- The protection should be extended to professional users who are frequently exposed during their private and professional life, during long periods of time and sometimes without proper protection or training.
- REACH must strengthen the mandate of the Commission by indicating an explicit preference for group approaches, and allowing the assessment techniques that make it possible (read-across, etc.).

8.5 What else is missing

Ease the burden for ordinary restrictions. Authorities' high burden of proof in the context of Article 68(1) vis-á-vis poor availability of risk information create the main bottleneck for the functioning of the ordinary restriction procedure. The Commission is considering measures to improve availability of data (see Section 6.3). But more can be done to reduce administrative burden when establishing proof of risk.

The Commission should adapt the interplay of the restriction dossier and Annex I REACH, for which the dual role of restriction and registration did not work, by giving to the dossier submitter more leeway on which risk assessment steps to follow, and requiring a less granular assessment overall.

To that effect, smaller clarifications of the Annexes would suffice. Annex XV REACH states that the "*risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I*". Section 0.1 of Annex I REACH states that: "*The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled …*". Accordingly, one simple option would be to add a new Section 0.1a defining the parts that are relevant for authorities when establishing the risk and lack of adequate control thereof.

In addition, **a preference for group approaches should be introduced in the legal text**, explicitly allowing the assessment techniques that make it possible (read-across, etc.).

Expand the mandate. To ensure a high level of protection, procedural rights of Member States must not be restricted (see on RMOA Section 6.1.3) but should rather be expanded. **Member States should be granted the right initiate fast-track restrictions under Article 68(2).**

9. Enforcement

ClientEarth appreciates the considerations by the Commission on establishing a European Audit Capacity to ensure a level playing field when it comes to enforcement. The current approach leaving broad discretion to Member States how to set up their enforcement systems has failed. To properly incentivize Member States to bring their enforcement in line with EU standards, **the audit system should be built upon binding legal criteria**.

Considerations in the context of the REACH revision seem to be limited to foster harmonisation of enforcement activities – while not tackling the grave differences in the sanctions systems established by Mamber States. Introducing a revocation mechanism would indeed create a sanction harmonised at EU level which creates strong incentives for registrants to keep their dossiers in compliance (Section 2.3). Accordingly**, penalties following violations of other REACH obligations have to be harmonised as well.**

Regarding obligations under the Authorisation regime, for example, a high level of non-compliance has been detected, with 40% of controlled companies having been found violating the law. Following detection of a non-compliance, the most common response of the authorities was 'written advice', though. Anticipating a 'written advice' note is obviously not a strong driver for companies to keep their business in compliance. In other words, this soft approach to sanctions taken by Mamber States may even contribute the high share of non-compliance.[25] **No Member State wishes to be the first mover stepping up their approach to sanctions**, due to possible implications for competitiveness. In this situation, **the REACH revision provides an opportunity to create an EU harmonised sanctions approach by introducing binding criteria, thresholds etc. for penalties**.[26] Regulation (EU) 2023/1115 on commodities and products associated with deforestation is one recent example showing that to ensure sanctions are effective, proportionate and dissuasive, minimum penalties can be introduced at EU level.

In addition, to enhance transparency, the Commission should revise the reporting obligations of Member States under Article 117(1), set up public registers of grave infringements and finally ensure

[25] For more details see the report Catch them 'cause you can | ClientEarth (2024).
[26] See the overview at Demand #5 for REACH reform: Sanctions & control | ClientEarth (2023).

transparency of non-compliance, or ‘name and shame’, via a public, and searchable, database of non-compliant companies.[27]

10. Access to Justice

ClientEarth strongly supports considerations to include in REACH a “*New provision allowing natural and legal persons to submit substantiated concerns to competent authorities (regarding non-compliance by other natural or legal person with REACH)*”. While we agree with the envisaged obligation of authorities to assess the concerns, take necessary steps and inform the person raising the concerns of follow-up, additionally **incentives are needed to ensure authorities take submitted concerns seriously**. To that effect we suggest adding a right for the submitter to challenge the decision taken by the authority.

Furthermore, there is evidence that people damaged by chemical exposure caused for example by chemical plants struggle to obtain effective legal protection in their national judiciary systems – despite commitments under the Arhus Convention of all EU Member States to grant effective access to justice in environmental matters. **The REACH revision is a prime opportunity to establish EU harmonised access to effective legal remedies, including the right to compensation and injunctive relief,** to those who have been harmed by exposure to chemicals.[28]

[27] For more details on these options see Catch them 'cause you can | ClientEarth (2024), p. 38.
[28] For more details see Demand #6 for REACH reform: Access to justice | ClientEarth (2023).

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