

Comments on Doc. CA/03/2022

REACH restriction & authorisation - options

We want to thank and congratulate the Commission for the progresses made and creativity deployed. We hope our comments will help adjust the proposal to reduce the burden on authorities without sacrificing a meaningful level of scrutiny – which we fear the t proposal, particularly option 2, does.

Solving current issues – state of play

There is no remedy without accurate diagnostic. The table indicates which dysfunction of the current system the Commission addresses fully (green), partially (orange), not (red) or worsen (several Xs).

	Issues to address	Current proposal
Information on use and alternatives	<ul style="list-style-type: none"> - Too little, too late - Alternative providers stay out - No compliance incentive - Lack “active” investigation tool 	<ul style="list-style-type: none"> ✓ ✗ ✗ ✗
Control of hazardous chemicals	<ul style="list-style-type: none"> - Annex XIV - slowly forsaken - 68.2 not used enough - 68.2 limited scope - 68.2 for COM only - 68.1 too hard, esp. health - No common objective - No explicit preference for broad restriction 	<ul style="list-style-type: none"> ∨ ∨ ✓ ✗ ✗ ∨ ✗
Requests for exception (authorisation or restriction)	<ul style="list-style-type: none"> - Legal “escapes” - Too many requests - Requests with poor justification - Hard to say no - Contentious yes 	<ul style="list-style-type: none"> ✓ ∨ ∨ ✗✗ ✗✗✗

Solving current issues – way forward

Information on use & alternative: Use it? Say it, Sort it

- ✓ **Notification obligation** – from register of intention and candidate list of detailed information on use & alternative
- ✓ **Active information tool** – market survey and investigation power (compulsory question to any company)
- ✓ **Compliance incentive** (no exception to future ban if non-compliance with info obligation)

Restriction: make space for best

- ✓ **Incentive for substitution**
 - Fees on use & foreseeable, quick phase out.
 - Obligation to do a substitution plan from candidate list & Support to substitution
- ✓ **Easy-to-adopt broad and precautionary restrictions**
 - No compulsory pre-listing for 68.1
 - Stated goal to minimise emissions and stated preference for broad scope
- Member States can trigger, directly or indirectly, 68.2
- 68.2 expanded to PBT, vPvB, PMT, vPvM, EDCs and later immunotoxicants and reprotoxicants as well as to professional uses
- 68.1 eased up (unacceptable use triggers the restriction, requirement closer to PBT restriction regime to build the dossier, refocused role for SEAC and RAC)
- Quicker transition from candidate list to annex XIV

Handling exceptions: easy no, constrained yes

- ✓ **Filter requests – less are allowed**
 - More and stronger barriers: essential use, compliance with information obligation, conformity & completeness checks
 - Fully documented “bridging application” or critical uses without alternatives receive short transition period with entry on Annex XIV
- **There is a role for authorisation, if reformed**
 - One route, no SEA: critical use without alternative, with substitution plan & risk minimised. Refocused role for SEAC
- AfA with similar uses must be joined, better definition of scope (intermediate, definition of use)
- Deadline for final decision, short grace period if rejected
- ✓ **End separation restriction/authorisation**
 - Restrictions can send some uses to authorisation (with deadlines & eligibility criteria)
 - Both can be adopted in parallel (level playing field)
- ✓ **Stricter regime**
 - Fees, monitoring, reporting

Zooming in - comments on the options

Section 3.1 Candidate list

We support the idea of maintaining the Candidate list and reinforcing its role as an information gathering tool and substitution incentive. We oppose turning the Candidate list into a systematic compulsory pre-step for restrictions.

To keep

- Make the candidate list a more powerful information tool, knowing that:
 - It must lead to the notification of detailed information on use, volumes and alternative
 - This obligation should add to – and not replace -reinforced registration obligations
 - Article 33 should be amended in parallel to make compulsory the information identified by ECHA, in the context of the SCIP database, as needed but without a legal basis for compulsory notification.
- Substitution incentive in the form of fees

To drop

- The candidate list must not become a compulsory pre-step to 68.1 or 68.2 restrictions. This would delay the process, and undermine the most ambitious or complex restrictions: broad, precautionary, non-intentional uses/degradation products.

To add

- Incentive for compliance with the obligation to notify information (for ex. cannot ask for authorisation/derogation later in the process if has not complied). Experience showed that non-compliance is common, which might happen again here as there is a double risk for companies in giving the information (restrictions + fees).
- The fast-track SVHC identification for substance with harmonised classification under CLP is a great idea, the reciprocal should also apply (fast track CLH if identified as SVHC) to save resources.
- Possibility for ECHA to use the fee budget for systematic market surveys, to identify alternatives.
- Power for ECHA to ask any company (SVHC producer, user, alternative provider, user, competitor) question to clarify the conditions of use and alternative state of play – similar to investigative power under competition law.
Those last two are indispensable to ensure that the experience of alternative users and providers will be known and integrated to the process – this is one of the main lessons of the last 10 years.

Section 3.2 Policy option 1

3.2.1 Prioritisation and inclusion of substances into Annex XIV

We support the idea of a quicker and more foreseeable evolution from candidate list to restriction (annex XIV and/or restrictions).

To keep

- Addition to prioritisation criteria
- Deadline for the Commission to amend Annex XIV
- No or simplified consultation

To clarify

- It is unclear whether the amendment of Article 58.2 is meant to prevent exemptions or extend the exemptions which can be set. If the intention is the latter, detailed reasons need to be given to justify this weakening of the scope.

3.2.2 Application for authorisation

The reform of the authorisation system must improve the system by 1) restricting the number of situations eligible for authorisation 2) closing legal escapes 3) make it easy to say “no” 4) make it easy to properly regulate the “yes”. The proposal of the Commission makes progress in this direction but needs to add elements to bring the system forward, which will better balance the need to reduce the workload while maintaining a meaningful level of scrutiny.

To keep

- Clearer definition of intermediate, use, exempted uses, suitability of alternative
- Adoption of “reporting standards” via REACH or guidance, definition of conformity and review report requirements
- Increasing fees and requirements
- Grace period for rejected application, if short

To drop

- Lighter requirements/process for risk “likely to be more controlled” or under a threshold of exposure/quantity used/emissions. Controlled used and minimised emissions must be a common requirement for all essential use, and many SVHCs are non-threshold substances.

To add

- Only critical use without alternatives are “acceptable use” of SVHC and therefore may be eligible for authorisation.
- Only joined application for similar, specific use must be allowed. No upstream.

- There should be only one route for authorisation, submitted to the following conditions: critical use without alternatives, risk minimised, detailed and reliable substitution plan showing credible effort to substitute quickly. The requirement to submit a socio-economic assessment must end – it is structurally unfit to require companies to consider wide societal impact and the individual impact on the company may be considered as part of the substitution plan (economic feasibility). The role of SEAC would be refocused on alternative and substitution plan assessment, which would require an adaptation of the composition.

3.2.3 Evaluation of applications for authorisations and opinion making

The necessity for a more formal check of the eligibility of some uses for authorisation is manifest, but it is not for a more formal intervention of the forum. A clear identification of what causes enforcement issues is needed to confirm that a change in the role of the forum is the solution.

To keep

- Formal (and stricter) completeness/conformity check

To drop

- The forum considers both the feasibility, “doability” of an obligation and its enforceability per se, the capacity to check whether there is compliance. In authorisation, the risk management measures are proposed by the company itself which should address the feasibility. On the enforceability:
 - The Commission is not clear on what are the problems, and therefore if the forum would be the adequate solution
 - Most of the issues are systematic, and should therefore be solved as such rather than by a case-by-case approach.

To add

- The completeness check should verify:
 - Whether the substitution plan is clear and helpful for the assessment (a similar approach to what is proposed for the exposure scenario).
 - Whether the use was considered earlier (modalities to defined) as non-critical or is not acceptable because an alternative for similar uses came to the knowledge of ECHA after the placement on the candidate list.

3.2.4 Decision-making process

We agree that the deadline should be extended to 6 months, but it is also crucial to add a compulsory deadline for the final decision.

3.2.5 Review of granted authorisations

We fully support the proposals of the Commission.

3.2.6. Short discussion on restriction process under Option 1

Opportunities that must be seized are missed in the current proposal, which therefore needs to be reviewed.

3.2.6.1 Restriction process under REACH art. 68.1

To add

- Reform of 68.1

Article 68.1 Restrictions will have an essential role to play in the future as showed by the list below. Making the process less heavy for the member states must be a priority. It is a massive and unacceptable gap in the current proposal.

Article 68.1 restrictions will be needed for:

- **Non-classic risk¹**, such as those caused by microplastics - the reference to the set list of end-points (CMR, and in the future EDC, PBT) by Article 68.2 does not allow actions for the risk that do not neatly fit those categories.
- **Very wide groups of substances** – even though it is not a requirement of Article 68.2, it has been so far interpreted as a tool to address classified or listed substances (rather than those “meeting the criteria” to avoid contentious discussion on the whether this condition is fulfilled). Wide group of substances generally contain both substances that are, and are not classified/listed;
- **“Emerging risk” defined as** “generally, those that have a high degree of uncertainty regarding the probability of occurrence and the amount of potential loss or harm²), for example those potentially caused by non-classified or listed substances, or those classified as category 2;
- **Risk by substances not classified/listed**, because not yet classified and listed – knowing that starting with this would delay the restriction too much - or breakdown products.
- **Situations not covered by Article 68.2** – Consumer products and category 2 CMRs, EDCs etc, Industrial use, contamination (non-intentional use), or group of substances for which there is a wide combination of situation (intentional, non-intentional, industrial, consumer, etc) that gains to be addressed by one measure for consistency and avoiding waste of resources;
- **Situations hard to cover by Article 68.2** - Substances in article from a wide variety of sectors that would gain to be addressed together, but are too complex to handle under Article 68.2.
- **Situations that could be addressed by Article 68.2 but are not prioritised** by the Commission.

¹ As described in Section 0.10 of Annex I “In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable [...]”

² Science for Environment Policy, Identifying emerging risks for environmental policy, Future Brief 13, 2016,p. 5 as reported in UBA, Advancing REACH: Strengthening control of emerging risk, 132/2021.

The following changes are needed:

- **Set a non-constrictive common vision of what justifies an EU restriction**, for dossier submitters to refer to rather than building everything case by case. This could be done by having a common goal – the minimisation of emissions and by setting the trigger for restriction as “unacceptable uses of substances of concern”.
 - **Allow for a more qualitative assessment of the risk and the proportionality**, closer to the regime applied today for non-threshold and PBT substances (with possibility to take adequate control into account in the derogations/transition periods).
 - **Strengthen the political willingness and capacity to adopt broad restrictions** (grouping, cross-sectoral uses) by adding an explicit preference for this approach in the text.
 - **Strengthen the political willingness and capacity to adopt precautionary measures** by anchoring the right to do so in the text and the method on how to do so in the annexes (and later, guidance) – for example by clarifying in Annex I the way to assess emerging risks and their consequences.
 - **Re-focus the role of the Committees on support rather than censure**, and on the scrutiny of the proposed derogations. Clarify the difference between the role of SEAC and the role of the Commission, and the respective roles of RAC/SEAC.
 - **Create a fairer share of burden between authorities and companies**: obligation for the companies to notify information on use from the entry on the register of intention without which no derogations can be granted, power to the member states to ask questions directly to companies (investigation power), criteria set in the text for eligibility to derogations (critical use without alternative, risk minimised)
- Abandoning the strict separation of Restriction and Authorisation

A more connected use of the two processes could benefit the system in two ways:

- Adopting a restriction in parallel when needed would help creating a level playing field for imported product
- Some uses which analysis block the restriction process could be sent to authorisation (with strict deadlines) under strict eligibility conditions and deadlines.

This would require an amendment of Article 58.5 among others.

3.2.6.2 Restriction process under REACH Art. 68.2

We strongly support the double extension of article 68.2, to professional use and EDC, PBT, vPvB, PMT, vPvM (and later to neurotoxicants and immunotoxicants).

The process to handle requests for transition periods and derogations must be clarified.

REACH should include an obligation for the Commission to present an annual plan on the proposal and adoption of 68.2 restrictions.

3.3 Policy Option 2: Merge the authorisation and restriction processes

3.3.1 Restriction under REACH Art. 68.1

See comments above on art 68.1.

The Forum already has the possibility to give an advice, and is consulted in the majority of case. The Commission is not clear on why making this possibility an obligation would bring an added value. Considering the additional burden on authorities and the process, the added value must be important and manifest.

3.3.2 Restriction under REACH Art.68.2

3.3.2.1 Restrictions following GRA

The extension of GRA is highly welcome, but the complex, multi-layer system of derogations imagined, without safeguards and eligibility criteria, creates the risk of lowering the scrutiny without lightening the workload for public authorities.

To keep

- The idea of a more agile set of regulatory tools to use for substances on the candidate list

To drop

- Making candidate listing a compulsory pre-step for art. 68.2 (which seems suggested in p.18 section 3.3.2.1)
- The adoption of a RoHS like system, because:
 - RoHS is known for killing incentive to develop alternatives, it has worked only to address low hanging fruits.
 - It would amount, in the context of REACH, to transferring the most contentious and difficult cases to the Commission. The workload associated with those cases was linked to their contentious aspects and vague information base. Lowering the scrutiny and taking away the safeguards (the proposal does not specify the conditions to which these derogations would be submitted) would therefore potentially raise the workload and length of the process by making it even more contentious.

To add

- An obligation to notify information from the register of intention or PACT for companies, and the power for ECHA to ask questions directly to the companies to inform the Commission's proposal
- The possibility to include longer transition periods for some uses from the outset is sound – but conditions for eligibility must be set in the text.
- In case of a critical use where it is still unclear whether there is no alternative or if the risks are minimised, the restriction could send back to authorisation, with deadlines.

3.3.2.2. Restrictions for SVHC

The entry on Annex XIV is already a general restriction of consumer, professional and consumer uses. Replacing this process by Art 68.1 restriction would make it considerably heavier. Replacing it by Art 68.2 extended to industrial use amounts to changing only the derogation process. We agree with the idea of having a more consistent approach to what is an unacceptable use for SVHCs and non SVHC restrictions. This is why we proposed in option 1 to have only one route for authorisation (critical use without alternative, with risk minimised and substitution plan, no SEA) and similar conditions for restrictions.

However, we oppose the derogation system proposed by the Commission:

To keep

- The idea that when sufficient information is available on the use, the Commission/Member States can propose longer transition period for some uses in the SVHC or non SVHC restriction (if these exceptions are submitted to eligibility criteria – critical use without alternative and with risk minimised)

To drop

- Generally applicable (joint) derogations, which proved to be killing incentive to substitution in RoHS and which would simply transfer the most contentious cases to the Commission without scrutiny and without, as now proposed by the Commission, criteria for eligibility/safeguard set.

It would be deeply non-sensical to reduce the scrutiny for the hardest cases and to keep it (RAC and SEAC + criteria) for the easiest cases (individual authorisation) as currently proposed by the Commission.

- Individual authorisations – should not be allowed or only exceptionally allowed, as it is highly improbable that a critical use without alternative would be filled by one company only across the EU. Joined applications for similar specific uses should be the norm and would avoid the workload now created by multiple similar AfAs.

To clarify

- Article 68.2 is open to substances that “meet the criteria” for CMR, and in the future other properties. It does not require a classification under CLP or a candidate listing. The Commission must commit to not limit 68.2 restriction to substances already listed/classified, and even more must commit to not wait for substances classified under CLP to get on the candidate list to consider them for restrictions – which would create undue delays.

3.4 Policy Option 3

When a problem is truly complex – as the conversion of the chemical economy – one needs as many tools as possible to solve it. Authorisation, if refocused and strengthened, has a role to play – particularly considering its capacity to establish scrutiny on sectoral uses, which requires information the restriction process often cannot unveil.

The substitution effect of the candidate list will be reduced if not linked to a foreseeable regulatory action. Worker law, that grew in effectiveness from the fear of a submission to REACH authorisation, might be weakened. In any case IED and worker law cannot, as REACH authorisation, create sectoral regimes for all SVHC uses – not create a strong incentive to phase out or exclude non-essential uses.

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