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Grouping of substances to be covered in a single restriction dossier (Restriction Task Force[1])

1. Background

Representatives of the Member States, ECHA and the European Commission discussed the possibilities to enhance the effectiveness of the restriction process by preparing restriction dossiers with a wider scope in the Restriction Workshop held in May 2017. Some Member States have also expressed their interest in promoting grouping in restrictions and asked for guidance on how to apply it in practice in their comments to the REACH review.

Discussions on this topic have continued in the Restriction Task Force (RTF) meetings of 30-31 January and was agreed in the meeting of 29 September 2020 and brought to CARACAL-37 of 17 November 2020. The content of this paper should be read together with the "fit-for-purpose dossiers – practical guide" available to Dossier Submitters via the support pages of ECHA's website here: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

2. Context

ECHA has moved from a substance-by-substance approach to addressing groups of structurally similar substances[2]. Most of the screening of groups is currently done by ECHA to help focus the resources of Member States on regulatory risk management actions[3].

This grouping approach:

- Brings consistency and improves the coherence of regulatory work;
- Makes it faster to identify substances that need regulatory action as well as those for which no further action is needed at this stage;
- Supports informed substitution by industry. Substances registered for intermediate uses only, or those not currently registered but which could be potential substitutes for known substances of concern, are also identified early on;

The groups of substances are primarily formed based on:

- Structural similarity, using the substance identity information in registration dossiers and C&L notifications; and
- Read across and categories, using information received in registration dossiers from industry and external sources.

Structurally similar substances are identified from all the registered substances (**the chemical universe**[4]). Certain substances are pre-selected to act as 'seeds'. ECHA's IT tools are then used to identify other substances that are structurally similar to the seeds.

[1] This paper was developed by the Restriction Task Force, consisting of representatives from Member State Restriction Dossier Submitters, ECHA's Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC) members and secretariat, and the Commission (DG ENV and DG GROW).
[2] "Working with groups" page on ECHA's website at: https://echa.europa.eu/working-with-groups
[3] Integrated regulatory strategy annual report "Grouping speeds up regulatory action" accessible: https://www.echa.europa.eu/documents/10162/27467748/irs_annual_report_2019_en.pdf/bd23e8cb-a55a-24af-4be3-7a29828ebb09
[4] Universe of registered substances, ECHA website: https://echa.europa.eu/universe-of-registered-substances

This provides a starting point for grouping substances that may eventually require regulatory action.

The possibility to group substances under one Annex XV restriction proposal has been used in many restrictions that have been adopted, are being adopted or are under discussion (see Annex I). The possibility for grouping is clearly discussed in the Guidance for the preparation of an Annex XV restriction dossier (Chapter 4.2.3 – see Annex II). In addition, some restriction proposals, or on-going studies, group substances for a specific use (e.g. on-going studies for a possible restriction on PFASs in firefighting foams and in textile and leather) rather than by the same hazard classes or the same exposure route (e.g. tattoo inks, skin sensitisers in textiles). The restriction on microplastics is an example of grouping on the basis of physical properties. Grouping possibilities may also depend on the envisaged conditions of the restriction i.e. a restriction targeted at specifying a limit value for the safety of humans or the environment may offer limited possibilities to capture more than a single chemical.

In addition, a number of restriction proposals (e.g. PFOA, its salts and related substances; BPA, or decaBDE) report concerns on the hazard or risk profile for at least one of the potential alternatives. These alternative substances may have harmonised classifications, be under substance evaluation, be proposed as substances of very high concern or subject to other regulatory risk management measures outside REACH but were not included in the restriction proposal. This could have been avoided by including the hazardous alternatives during preparation of the Annex XV restriction dossier.

These issues were some of the reasons behind ECHA's unique decision to move to working with groups of substances rather than individual substances (see RTF18_candidate-to-restrictionv2 for more information). The identification of these groups is currently performed on the basis of chemical structural similarity but could also be on the basis of similar uses in the future.

Up until now, even though there have been some concerns about the risks associated with alternative substances, the restrictions have continued to be implemented. In some cases, the restrictions have even helped to identify the most likely regrettable alternatives, which can then be monitored before and after the restriction enters into force. See the case of BPA in thermal paper and its alternative BPS (see https://echa.europa.eu/hot-topics/bisphenol-a). However, the traditional assessment by regulators of the substances one by one, and their corresponding substitution by industry, may cause delays in achieving full risk reduction capacity.

3. Benefits from grouping

The basic idea behind grouping is to have a higher risk reduction capacity for human health and the environment by increasing the number of relevant substances included in the scope. Industry also benefits from the approach in the sense of receiving more certainty on the substances to be restricted, and also by avoiding regrettable substitution and costly investment, while ensuring a level playing field between the producers and importers of the substances in the group and a better communication through the supply chain. The Dossier Submitters may save resources by managing the risk with one Annex XV restriction dossier and one restriction process, depending on the type of grouping / restriction.

Grouping seems appropriate when there are at least some similarities in the hazard or risk profiles of the covered substances (e.g. chemical similarities or same overarching concern, for example, on the uses, on the exposure route, or on the degradation process). One of the benefits of grouping substances is it also allows the DS to cover substances for which these profiles have not been (fully) established e.g. data is not available.

Combined exposure of highly similar substances, all contributing in a dose-additive way to the identified toxicological concern, can be accounted for in a single assessment. This is a benefit as it can underpin a proposed restriction option for the whole group, e.g. the 4 phthalates restriction. A similar mechanism and mode of action could form a solid basis for a grouping restriction. The information required for the analysis of alternatives (AoA) and the socio-economic analysis (SEA) does not necessarily increase if more substances are grouped under one proposal. The current practice is already that the Dossier Submitters assess alternatives which are preferred from a human health and environmental perspective and which do not necessarily imply an increase of the costs. The amount of additional work on demonstrating hazard and risk depends on how similar the grouped substances are, how data can be used through a read across, category and QSAR approaches and on the similarity of the uses for similar risks. Groups based on use could lead to additional information needs, therefore it is always convenient to gather as much as possible information on the exposure route. Groups based on substances could lead to the identification of the most prominent alternatives to several substances included in the group. These will need to be addressed in the Annex XV restriction dossier.

4. Challenges of the grouping approach

As mentioned in the benefits section above, Grouping seems appropriate when there are at least some similarities in the hazard or risk profiles of the covered substances. If these profiles have not been (fully) established e.g. as the scope covers substances for which data is not available, the justification of the grouping scope may be more challenging and subject to criticism, unless it is fully explained by the Dossier Submitter.

Another issue is that it may be challenging to actually assess the socio-economic implications of a restriction using grouping, in terms of e.g. costs for industry to comply or benefits to human health or the environment, when more than one, or an unknown number of substances (as was the case e.g. in the PFOA and related-substances restriction proposal (see Annex 2)), is concerned. This will very likely create uncertainties and require from the Dossier Submitter the use of assumptions (and the need to justify them) and of sensitivity scenarios. These assumptions should be tested in the consultation of the Annex XV restriction dossier.

The more substances that are included within the group, the more challenging their assessment is likely to be, in particular when they present a different hazard profile. There are no specific limits set so far in the number of substances that can be grouped together under a restriction proposal and each proposal will need to be evaluated individually, on a case-by-case basis. The tattoo inks restriction dealt with nearly 4 000 substances with many different hazard profiles because the exposure scenario was so specific.

Enforcement of the restriction for a group of substances may also present practical challenges. For efficient enforcement, the substances regulated should be established with sufficient clarity and analytical methods to allow determination with adequate reliability.

Ideally, analytical methods should be available for all substances included in a group or should be able to be developed before entry into force of the restrictions. However, as normal in restriction proposals, lack of a harmonised analytical method should not be an impediment to proposing and adopting a restriction.

5. Issues extracted from previous restriction cases

The RTF have compiled a number of examples of grouping used in restriction dossiers past and present (see Annex I). From these examples, the benefits, challenges and limitations of grouping substances under the restriction process are set out in Table 1.

6. Conclusion

The Restriction Task Force supports grouping to be used in restriction proposals, including proposals for substances having different hazard profile or an uncertain hazard profile but the same use. This grouping can include potential substances currently not on the market or commercially interesting (and hence having no exposure (yet)), based on assumptions that they could (in the future) contribute to the same concern. The main driver for this is to avoid regrettable substitution.

Table 1: benefits, challenges and limitations of grouping substances under the restriction process

Benefit	Challenge	Limitation	Example(s) (in Annex I)	Potential solution
	Identification of the substances included in the scope.		PFHxS PFOA (salts, and related substances) C9-C14 PFCAs Tattoo inks Skin sensitisers	Make generic scopes as clear as possible with derogations where individual substances do not fit the risk profile (for example). An indicative or a closed list in the Annex XV restriction dossier and Background Document is highly desirable for enforcement.
	Substances in scope but not proved to be in the products		Skin sensitisers Tattoo inks	If it is demonstrated that such substances may be used as an alternative, then the scope should be as clear as possible and supported by an indicative or a closed list
There may be some efficiency gains in describing the costs, use and alternatives if the substances are used in the same sector.	Substance specific hazard assessment (DNEL derivation), limited efficiency gains of grouping		Aprotic solvents (DNEL type restriction)	Grouping approach in DNEL-type restriction could be efficient if toxicological read-across is strong (i.e. metal ion responsible for toxicity).

Annex I: Examples of grouping

Group	Scope	Points to note
PFOA, its salts and related substances	The restriction on PFOA, its salts and related substances covered all the substances that are considered to degrade to PFOA. An indicative list of these substances is included in the Background Document, but many others exist. All substances which are known not to degrade to PFOA are excluded from the scope, but not all of the covered substances have experimental data on biodegradability. During the consultation on the Annex XV restriction dossier, stakeholders were invited to provide evidence on any substances in the scope of the restriction which would not degrade to PFOA.	Degradation was one of the main issues that RAC focused on in its evaluation. It was also qualitatively considered by SEAC in its discussions. Challenges in enforcement due to the non-availability of standardised analytical methods for the covered matrices.
PFASs (wide scope)	A restriction with a wide scope (all PFASs) is in the early phase of joint Member State development by DE, DK, NL, NO and SE, with support from ECHA. The European Commission carried out a study to assess if there is a need for regulatory action to control risks from PFASs in textiles and leather. This will be covered under the wide scope of this (joint) restriction proposal.	The main concern for the whole group will be persistency and the consequences of these substances being released to the environment. Hazardous properties of groups of PFASs will likely be qualitatively assessed as additional justification for a proposed EU-wide measure.
PFASs in firefighting foams	Some PFASs used in firefighting foams have been regulated in the EU by the restrictions on PFOS and PFOA. However, other PFASs including the C6-chemistry (reported to be the main alternative) are not necessarily any better from environmental perspective. Some of the	ECHA and the European Commission are finalising parallel projects in 2020 to assess if there is a need for regulatory action to control risks from PFAS containing firefighting foams. Data will be collected and assessed on the use of these firefighting foams and alternative

	alternatives are in different regulatory processes, including restriction.	fluorine-free or other PFAS-free foams, including their risks. The idea is to cover all PFASs substances if available data does not demonstrate that the described generic risk profile does not apply to specific substances. Justification for covering all relevant PFASs will be prepared by ECHA. This approach should allow to assess all potential alternatives for the use in fire-fighting foams and to conclude which are the most suitable ones for different types of fires, considering the function to be provided and the risks for the environment. This is an example of a grouping based on potential use in combination with chemical properties (perfluorinated alkyl functionality). The European Commission has recently requested that ECHA prepares a restriction proposal for PFASs fire-fighting foams and submission is expected by the end of 2021.
Aprotic solvents	A risk management options analyses concluded restriction as the most appropriate measure to manage the risks of three registered large volume aprotic solvents NMP, DMF and DMAC. Others such as NEP could be added.	The regulatory approach followed for these solvents classified as Repro Cat 1B was based on their widespread use in industrial and professional settings and by considering their interchangeability of application on site. For practical reasons, the substances were not grouped into a single Annex XV restriction dossier. The Netherlands in 2012 submitted an Annex XV restriction dossier on NMP and Italy followed in 2018 with a dossier on DMF. The Netherlands have also submitted an intention to

		prepare a restriction dossier for DMAC and NEP foreseen for submission in October 2020. Although this approach will benefit the registration dossier in terms of values of DNELs and the communication through the supply chain with consistency in the safety data sheets, the restriction does not specify the risk management measures needed to control the exposure for uses in different industrial sectors below the DNEL values set up by the regulations. It remains a case for future similar restrictions, how effective can the control of the exposure at the workplace be, by setting up DNEL under restrictions instead of better harmonisation of risk management measures and operational conditions for specific and target uses of the chemicals. This is an approach that should also be considered and further explored not only in terms of effectiveness but also in terms of practicality, and monitorability of the restriction.
Skin Sensitisers in textiles	The 2019 French-Swedish restriction proposal on skin sensitisers covers more than 1000 chemical substances. It covers all substances with harmonised classification as skin sensitisers in Category 1/1A/1B according to Annex VI of CLP Regulation as well as a list of substances of concern (disperse dyes).	This proposal aimed to reduce the risk for skin sensitisation to substances in finished clothing, footwear and textile, leather, fur, hide and synthetic leather articles with similar skin contact to general population. A large number of substances are used intentionally in those articles or are generated unintentionally during articles processing. The available data concerning which substances can be found in

		the articles at point of sale was not considered sufficiently reliable and comprehensive to base a restriction in terms of individual substances. The number of substances used in the manufacturing of the articles is high, many of them are unknown and the substances used may change with time on this very volatile and fashion-dependent market. It is acknowledged that not all substances within the scope will be used in the production of articles covered, and not all will be present in the finished article at point of sale. However, an approach that would have restricted individual substances would have had the disadvantage of not capturing all skin sensitising substances (including substitutes) and hence, it would not have fulfilled the objective of the proposal. A more limited scope approach would have led to regrettable substitution and a reduced risk reduction capacity. The dynamic relationship to CLP Regulation was considered the best protective approach also given that skin sensitisation is not a prioritised hazard category for harmonised classification under CLP and many chemicals with skin allergenic properties may not be classified as skin sensitisers. The Dossier Submitter included some disperse dyes (without harmonised classification) in the scope because they are proved to have skin sensitising properties and are included in voluntary labelling schemes.

Microplastics	ECHA has proposed a restriction for all polymers (according to Article 3(20) of REACH) in solid particles.	The risk assessment is based on paragraph 0.10 of Annex I and is based on 'extreme' persistence in the environment leading to an increasing environmental stock. The grouping approach was used related to the risk vs the polymers. Exemptions were given for natural, biodegradable and soluble polymers (as these do not fit the risk profile). The precise and criteria for determining them were included in the restriction proposal.
Tattoo inks and permanent make up	The scope of the restriction covers a high number of substances potentially used in tattoo ink and permanent *make up*. A grouping approach was applied based on hazards considering the specific way of exposure i.e. injection under the skin and permanent contact with human body. The groups of substances covered are: • Substances included based on their harmonised classification(s) as: ○ Carcinogenic or mutagenic (CM), categories 1A, 1B or 2. Azo colourants that are not classified as CM category 1 or 2 but may undergo decomposition to or contain residual aromatic amines that are so classified, are also included.	The preparation of the Annex XV restriction dossier was a challenge, but the clarity of its scope allowed a good discussion and assessment by the ECHA's Committees as well as for the consultation during the preparation of the Annex XV restriction dossier. This example put together by four Member States plus ECHA, and the collaboration is continuing before its entry into application through exchanges of the enforcement authorities (Forum) on the availability of analytical methods.

	○ Toxic to reproduction, categories 1A and 1B and 2 ○ Skin sensitisers, skin corrosives, skin or serious eye damage or irritants. • Substances included in the restriction based on their inclusion in the Cosmetic Products Regulation (CPR), i.e., substances on: ○ Annex II of the CPR (the list of substances prohibited in cosmetic products) ○ Annex IV of the CPR (positive list of colourants allowed in cosmetic products with some use or concentration restrictions). • Substances included in the restriction based on the REACH Annex XVII (and national legislation) and not considered in the previous categories: ○ Five substances in Table 3 of ResAP (2008) ○ 14 colourants in Table 2 of ResAP (2008) without harmonised classification and not included in point 1 above. In total, more than 4000 substances fall within the scope of this restriction proposal (in the categories described above).	

DecaBDE	DecaBDE is included in the restriction due to PBT/vPvB concerns. Uses included as a flame retardant in plastics and textiles. There were also some other uses in adhesives etc. about which little was known.	As the uses were minor they were assumed to be negligible compared to the other uses. In addition, an alternative (EBP) was identified which was suspected to have similar effects, this substance could have been included in the Deca-BDE restriction, although the issues surrounding the hazard identification of EBP would likely still have come up.
Bisphenol A	France proposed a restriction for BPA in thermal paper.	The restriction was agreed but RAC had concerns with BPS the most likely substitute. This was suspected to have similar effects and could give rise to similar concerns. BPS could have been included in the BPA restriction. The main challenge would have been to bridge the gap in the level of knowledge between both chemicals on the risks associated with the use in thermal paper. BPS was at the stage of RMOA when the restriction proposal for BPA in thermal paper was established based on its well-studied endocrine disrupting properties.
Siloxanes	The UK proposed a restriction on wash off cosmetics containing D4/D5, ECHA was requested by Commission to make a restriction on D4-D5 on other uses but during the preparation of the restriction D6 was identified as an PBT and added to the scope. Other (PBT/vPvP) substances with a similar use profile could also have been included.	