Recommendations of the Task Force on Restriction Efficiency

Efficiency:

- The extent to which time, effort or cost is well used for the intended task or purpose.
- The capability of a specific application of effort to produce a specific outcome effectively with minimum waste, expense, or unnecessary effort

In the context of this project, efficiency should be understood as efficiency of the restriction process as a whole – including the dossier preparation.

Introduction

Background

The Member State Competent Authorities (MSCAs), the Commission and ECHA raised concerns in the past about the work load relating to preparing restrictions and have urged that the efficiency of the opinion making process should be improved. Some key elements raised with regard to the preparation and evaluation of the Annex XV restriction reports were:

- workload of Member States and ECHA (including the Committees) in the preparation of Annex XV restriction reports
- workload of the Committees and Member States in the management and evaluation of Annex XV restriction reports

The issues raised were discussed in CARACAL (March and November 2013) and in ECHA's Management Board and its working group on planning and reporting (June and September 2013).

The Commission, ECHA and MSCAs share the concerns about the quality of the Annex XV restriction reports and the functioning of the restriction process. At the same time, it should be recognised that, while restrictions themselves have been prepared and agreed under the previous legislation, the restriction process under REACH has introduced some new elements and requirements. These, as well as the new procedure, pose challenges for all parties involved[1].

[1] Commencing in 2009, there is a requirement for MS (or the Commission instructing ECHA) to initiate the restriction process via an Annex XV restrictions dossier, in a similar way to an ESR Risk Assessment and Risk Reduction Strategy as well as the Commission's proposal for the restriction (including the Impact Assessment). This sets a new set of requirements for a formal conformity check of the dossier and the preparation of the opinions of RAC and SEAC. The opinions are the basis for the Commission to propose an amendment to Annex XVII (restrictions).

Work of the Restriction Efficiency Task Force (RETF)

The RETF was set up following the CARACAL meeting of November 2013 to:

- Bring Member States, ECHA's committees and secretariat, and the Commission to the table, and
- Make coherent recommendations for improving the efficiency of the restriction process.

To prepare for this work a survey of Member States, RAC and SEAC members, and stakeholders was carried out from December 2013 to January 2014. Responses were received from 64 parties, which were then analysed by the ECHA secretariat to provide one input to the RETF work (Annex I gives an overview of responses). Other initial inputs to the work included the Commission's CARACAL paper of 27-28 November 2013 (CACS/23/2013), several position papers by Member States, previous efficiency project work by ECHA and the Task Force's own expertise. A list of participants in the Task Force can be found in Annex II.

The REFT met face-to-face, 3 times in 2014 (6 February, 7 May and 8-9 October 2014) and once by Webex (18 March 2014). During the process feedback was given to CARACAL, RAC and SEAC on a number of occasions.

The RETF agreed to discuss and agree key observations and recommendations under the following headings (that were distilled from ECHA's analysis of the questionnaire):

- Opinion making procedures in Committees
- Extent of analysis required (dossiers and opinions)
- Main challenges in preparing proposals
- Scope and targeting
- Proportionality
- Technicalities (Annex XV format, guidance)

Results

The Restriction Efficiency Task Force (RETF) has agreed on about 90 Recommendations since its inception in 2014. The original RETF endorsed 57 recommendations (many that were addressing more than 1 actor) related to the 6 headings previously mentioned above. Thirty three additional recommendations have been identified at the regular restriction workshops that ECHA holds with the Member States and the Commission, which were then endorsed by the RETF members (see

Annex II for details)[2]. The following table gives an overview of whom the recommendations are addressed to:

Actor	Number of recommendations relating to each actor.
Commission	11
ECHA	63
Member States	28
Committees	36

The agreed recommendations (Annex III gives a complete list of recommendations and their status) give concrete examples of how the restriction process can be improved from the perspectives of Dossier Submitters (MSCAs or ECHA) as well as the Committees (during decision making stage). The proposals will also improve the Public Consultation process during the opinion making stage.

To respond to some of the recommendations agreed by the RETF, two separate papers were drafted and agreed at the RETF:

- Dossier Submitters' and ECHA Restriction Team's involvement in the restriction process (Annex IV).
- Setting a clear scope: A common understanding for a clear scope of Annex XV restriction proposals (Annex V).

The contents of these papers now provide a solid basis to assist with the implementation of other recommendations.

In addition, the preparation of several other papers has been recommended and these will be published on ECHAs website as they become available.

Conclusion

The Recommendations have been instrumental in improving the efficiency and effectiveness of the restriction process and their effect has been visible in Dossiers received and in the work of the Committees.

[2] Currently the former RETF members are consulted ad-hoc on recommendations on papers related to the efficiency or effectiveness of the restrictions process (see later in the paper for further discussion on this).

Annex I: Summary of survey results

The survey was answered by 64 respondents:

- 17 from MSCAs (but only 12 unique Member States)
- 21 RAC members
- 23 SEAC members
- 3 stakeholders

The main issues raised by Member State Competent Authorities were:

- Widespread problems with data collection from industry, help from ECHA wanted
- Some dissatisfaction with Annex XV format (repetitiveness)
- Member States who have not submitted restriction reports yet raise the issue of lack of competence and/or resources and would like to cooperate with other MS while DS have sufficient resources and are sceptical cooperation would reduce workload
- CSRs from registrations widely regarded as insufficient as data source
- DS are more critical of guidance than non-DS (difficulties in particular with cost and benefits assessment)
- Non-DS tend to think unclear scope would lead to non-conformity, DS tend to differ
- Strong dissatisfaction of DS with RAC/SEAC (especially requests for additional information)
- Most members think unclear scope hinders opinion making and would lead to non-conformity

The main issues raised by ECHA's Committees were:

- SEAC's difficulties tracing cost estimates in dossiers are somewhat greater than RAC's difficulties tracing risk estimates
- Members and rapporteurs in particular would prefer more structured/targeted and less detailed/lengthy plenary discussions (SEAC even more so than RAC), general support for ad-hoc groups
- Division between RAC and SEAC quite clear but SEAC feels better informed about RAC developments than vice versa
- Rapporteurs more critical of support from other members than of dossier quality

- Diverging views on usefulness of BD and who should update it.
- Very high approval of support from ECHA restriction team but ECHA restriction team role in opinion making sometimes unclear
- RAC: Support for consolidation of common issues by ECHA committees secretariat
- SEAC: Cost information in part E and SEA in part F both essential for opinion making (rapporteurs less strong on this than non-rapporteurs)

The main issues raised by stakeholders (one response each from industry association, environmental NGO and a national council of chemists) were:

- Conflicting views on appropriate scope of restriction proposals and on burden of proof placed on DS
- Generally low level of satisfaction with consultation process (both the industry association and the NGO mostly do not feel comments are properly taken into account)
- Key issue: Reaching and getting information from downstream users

Annex II: RETF members (May 2018)

SEAC member	Simone FANKHAUSER
SEAC member	Johanna KIISKI
RAC member	Michael NEUMANN
RAC member	Sonja KAPELARI
Denmark	Lars FOCK
Norway	Heidi MORKA
Sweden	Helena DORTH
Germany	Eva BECKER
France	Karine FIORE
Netherlands	Richard LUIT
DG GROW	Manol BENGYUZOV
DG ENV	Giuseppina LUVARA
ECHA	Mark BLAINEY (Chair)
ECHA	Tim BOWMER

Previous members: Andrew SMITH (RAC); Boguslav BARANSKI (RAC); Frank JENSEN (DK); Dag LESTANDER (SE); Remi LEFEVRE (DG ENV).

Annex III: Key observations and recommendations made by the RETF

1. Original RETF recommendations

1	Main challenges in preparing proposals	
Key observations:		
• Some MS lack competence to prepare Restriction dossiers • Co-operation with 'experienced' MS might assist less experienced MS to prepare dossiers. • Data collection from industry difficult (key aspect needing further exploration) • Information from CSRs was not always available or used (useful) in preparing dossiers; international reviews were used when published by internationally recognised organisation to challenge the CSR • Dossier submitter may themselves sometimes have to undertake the detailed assessment when information is missing in the CSR		
Recommendations		
	Action actor	*Implementation progress?*
Possibility for Dossier Submitters to meet bilaterally with ECHA > 6-9 months before submission of dossier (PRIM – Pre-Restriction Information Meeting): • A clear scope is a key issue to discuss • Enforcement issues as a standard agenda point.	ECHA and MS	Completed
If requested, ECHA to 'host' Dossier Submitter's call for evidence to provide access to > 15000 newsletter recipients.	ECHA and MS	Completed
Provide a forum for the Dossier Submitter (if required) to discuss key issues (e.g. scope) with other Member States before submission.	ECHA	Completed
COM engaged early in the process in particular when discussing the impact on	COM	Completed

other EU legislations both during RMO discussions and during dossier preparation through discussions with ECHA.		
Member States encouraged to work together or provide a possible pool of experienced DS contacts; those who gained more experience should share this experience with others to stimulate their participation.	MS	Completed
MSCAs are suggested to consult their national Forum member at the drafting stage (before the dossier is submitted to ECHA) and National Forum member to cooperate with MSCA during the drafting process.	MS	Completed
MSCAs and Forum members from submitting countries to take into account the Forum guide for developing Forum advice on Enforceability of Restriction Proposals (GDAERF), in addition to the Annex XV guidance, as help for the assessment of the enforceability of the Annex XV proposals	ECHA and MS	Completed
GDAERF to be revised by Forum and then consulted with MSCAs to promote a common understanding of the enforceability assessment.		
Other resources to be made available by ECHA - may be considered by dossier submitter and Forum member to assess enforceability.	ECHA	Completed

2	**Extent of analysis required (restriction dossiers and opinions)**

Key observations:

- Committees made unreasonable requests (from DS perspective) for additional information. There is a need to clarify with DS when Committees make requests for additional information.
- Dossiers have been so far of good quality (RAC/SEAC).
- It is not yet clear for the DS how detailed the analysis needs to be for the Committees to develop their opinions.
- RAC and SEAC are not mandated to give an opinion on whether the risk is unacceptable but should focus on estimating the risks and impacts.

Recommendations

Recommendation	*Action actor*	*Implementation progress?*
Dossier Submitter to highlight key issues in dossiers, including uncertainties (e.g. in the scope), to focus and facilitate the evaluation of RAC/SEAC (e.g. in specific boxes).	MS, ECHA-S	Completed
ECHA (and Committees) to further clarify the role of the Restriction Team in the restriction process.	ECHA-S	Completed
ECHA will consolidate appropriate RAC/SEAC analysis and methodology on specific cases for future reference.	ECHA-S and Committees	Completed
COM to present to Committees their expectations after the implementation of these recommendations and the aspects that are the remit of the Commission such as the legal wording of the proposed restriction.	COM	Completed
Committees to make opinions on the DS proposal (following provision of information requested at conformity) except for clearly justified requests for clarifications by committees. However:	ECHA-S and Committees	Completed

• If requested information is not available, then this should be clearly communicated to the Committees by the DS and this information should be specifically requested in the PC. The absence of key information could then be flagged under the heading of 'uncertainties' in the opinion. • In the absence of information, assumptions should be clearly indicated by the DS, so that Committees can assess these assumptions, and the PC contradict them or not. • It is recognised that the failure to provide additional key information by the Dossier Submitter or through Public Consultation could potentially lead to an opinion that the proposed restriction (relevant issue) cannot be assessed. • Industry not providing data during the Public Consultation or confirming assumptions made should not be a reason for the Committees to conclude the proposed restriction (relevant issue) cannot be assessed; COM/ECHA/MS should explore mechanisms to improve industry input in this regard.		
Establishment for when and what purpose further information is required from the DS by the Committees. Requests should be prioritised.	ECHA-S and Committees	Completed
Common approach paper to be developed for the restriction process.	ECHA-S, COM and Committees	Completed
RAC should analyse exposure scenarios in the proposal and ensure they are clearly described.	ECHA-S and Committees	Completed
The opinions should be based on an assessment of the information in the background document.	ECHA-S and Committees	Completed

Diligent documentation of the effort made to collect information and consultations made.	ECHA-S and Committees	Completed
If additional information brought up by the PC does not have a supporting justification which would help RAC/SEAC in its analysis, then the information will not be taken into account by RAC/SEAC; this should be made clear when launching the PC.	ECHA-S and Committees	Completed
It is not the task of RAC/SEAC/ECHA RT to collect new data.	ECHA-S and Committees	Completed
There should be more communication between the rapporteur and the DS during opinion making in terms of presentation of information in the Background document; this should be resolved in the 1st dialogue if possible.	ECHA-S and Committees	Completed
Review the RCOM format/procedure in terms of grouping comments and responses, clarify who should make the final version of the RCOM.	ECHA-S and Committees	Under consideration

3	**Opinion making procedures in Committees and public consultation**

Key observations:

- Chairmen should curtail superfluous discussions; more guidance or examples of where discussions of low regulatory relevance were not needed could be helpful.
- More pragmatic use of ad-hoc groups and newsgroups during and between plenaries.
- Committee members could provide more support to Rapporteurs.
- ECHA's Restriction Team has helped but their role needs further clarification.
- Conformity check is about right (check of information as per template, not evaluation) but needs to be more focussed on the critical issues for PC and opinion making.

Recommendations

Recommendation	*Action actor*	*Implementation progress?*
Dossier Submitters status as observers is confirmed at RAC/SEAC meetings, including at conformity check stage, including possibility to answer questions if raised by the Committee.	ECHA-S and Committees	Completed
Continued use of ad-hoc groups and discussion fora at and, when planned for, between RAC/SEAC meetings; non-committee members to be invited at the discretion of the Committee.	ECHA-S and Committees	Completed
Review ECHA's opinion making procedure (in light of final recommendations).	ECHA-S and Committees	Completed
DS role in opinion making process to be clarified especially to highlight where they are expected to give input into the process.	MS, ECHA-S and Committees	Completed
Identify Committee members to support Rapporteurs.	ECHA-S and Committees	Completed

RAC and SEAC should focus on the evaluation of the information in the Annex XV dossier and any additional elements submitted during public consultation process to fulfil their task of formulating an opinion: • as to whether the suggested restriction is appropriate in reducing the risk (RAC); • on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact (SEAC).	ECHA-S and Committees	Completed
Possible clarification from COM could be sent in writing during the opinion making process as early as possible.	COM	Completed
No final legal text required in RAC/SEAC opinions (only clear elements what should be restricted and what should be derogated to be included in the proposal with clear justification in the opinion and BD); the Annex XV dossier should include the restriction proposal, which should be fully assessed.	ECHA-S and Committees	Completed
More dialogue is encouraged between the Rapporteurs and DS before the conformity check. • Dossier submitted 2 weeks earlier and dialogue thus possible between DS and Rapporteurs related to CC.	ECHA-S, MS and Committees	Completed
CC recommendations targeted on essential issues and prioritised for both incorporation in the BD and for the PC.	ECHA-S and Committees	Completed
To alert interested parties to the public consultation, ECHA should proactively contact: • Registrants and all C&L notifiers of substances being subject of a restriction proposal,	ECHA-S	Completed

• registrants and C&L notifiers of alternatives covered by Annex XV dossier, • downstream users, if possible, and • other stakeholders, including NGOs.		
Encourage SMEs (and others) to sign up for ECHA news alerts: • Joint campaign with stakeholder to publicise ECHA news alerts as a means for information on restrictions (amongst other issues); • Sharing of relevant contact lists; • Work with CEFIC/UAPME etc. how to better contact DU.	ECHA-S	Completed
MS to publicise ROI and PC - target to own stakeholders.	MS and ECHA-S	Completed
A description of what kind of information is expected from potential respondents, and for what purpose in the process, should also be provided • Information note to make clear scope, key issues (linked to recommendations); • A list of questions should be more systematically used to address the key issues, including socio-economic issues.	ECHA-S	Completed
ECHA will work on how companies and other stakeholders should submit their comments via the public consultation, to collect the maximum amount of information needed by RAC and SEAC during their opinion-making in the restriction process. • Encourage answering key issues questions; • Encourage answering within 5 months but leave open for 6 as this is the official legal end of the PC;	ECHA-S	Under discussion

• Information arriving after the PC will not be taken into account by RAC/SEAC but will be made available to the Commission.		

4	Scope and targeting	
Key observations:		
• Possible to define clear and coherent scope. • Unclear scope should be considered during the conformity check. • Derogations are part of the scope and as such are to be assessed by RAC/SEAC.		
Recommendations		
Recommendation	*Action actor*	*Implementation progress?*
COM/ECHA/MS/Committees should clarify how they define a clear scope in the conformity check and the opinion making process: • Note+ (with examples of initial XV dossiers vs final Annex XVII entry and checklist) by COM with input from TF. • Guidance for DS and Rapporteurs/Committees	COM/ECHA/MS/Committees	Completed
Substance ID to be clear (normally EC/CAS or groups, grouping justified) – ECHA to provide SID 'service' when requested by DS.	MS and ECHA-S	Completed
The DS should explicitly state if the actual scope of the proposal excludes part of the potential scope (e.g. consumer products vs consumer products for 0-36 month children) and this sets the scope of the assessment for PC and for assessment by the Committees.	MS	Completed
Derogations which have been fully assessed within the Annex XV dossier will be assessed by RAC/SEAC.	ECHA-S and Committees	Completed

5	Proportionality

Key observations:

- Cost information is essential to be able to give a meaningful opinion. Without it SEAC would not be able to evaluate the resource implications to the society.
- Quantification of human health and environmental impacts and other SEA issues is preferable.
- However this is not always possible (for instance in the case of PBTs).
- SEAC's PBT working group recommendations helpful.
- Depth of analysis is case-dependent.
- In case there is little information on costs submitted during public consultation, it can be inferred that the concern is low, unless information about the process did not reach the adequate audience.
- If a Section F (SEA) is not available and no information/estimate is available in Section E on costs and risk/impact, SEAC would find it difficult to evaluate and give an opinion if the health or environmental impacts are higher or lower than the costs of the restriction; this information may be available in the PC.
- ECHA and SEAC should not fill any impacts (benefits) gap in the restriction proposal. However, during the preparation of the restriction report, ECHA may provide methodological assistance.
- All restriction proposals included a Section F (SEA).

Recommendations

Recommendation	*Action actor*	*Implementation progress?*
It is possible to improve access to data on costs through (commercial) databases: It is recommended that ECHA acquire access to a database that provides information on prices and quantities of substances sold in the EU and rest of the world and make this information available to Dossier Submitters, subject to any commercial/contractual conditions (i.e. data aggregation may be required).	ECHA-S	Ongoing
It is recommended that ECHA and COM discuss with Eurostat how it and MSCAs can	ECHA-S and COM	Ongoing

access (easiest) their databases on e.g. products, population data, foreign trade of the EU.		
Publicise to MS, SEAC's WG's report on how to assess PBTs and after validation assess if this approach is suitable for other endpoints.	ECHA-S	Completed
Use Network of REACH SEA and AoA Practitioners (NeRSAP), for example, to explore ways of obtaining data and to gather knowledge of e.g. technical and economic feasibility alternatives; MS are encouraged to actively participate.	ECHA-S, MS and COM.	Completed
DS must submit the following information to demonstrate proportionality: • an estimate of cost implications or savings (net costs) of the restriction as well as consideration of its risk reduction capacity, and if possible and meaningful quantification of the human health/environmental impacts.	MS	Completed
DS are encouraged to analyse socio-economic impacts in accordance with Annex XVI to support the restriction	MS	Completed
It is clearly recognised that the quantification of human health and environmental impacts is not always possible.	All	Completed
DS should investigate with any national institutes to obtain information e.g. costs of diseases.	MS	Completed
Step-by-step approach (as suggested in the SEA guidance document) necessary: • Identification of all potential impacts (e.g. economic, environmental, social, health); • Qualitative assessment of impacts (including an assessment of order of magnitude);	ECHA-S, MS and Committees	Completed

• Quantitative assessment of impacts (that are meaningful to quantify); • Quantify most significant impacts; • Approach likely to be iterative.		
When data is missing, use reasonable assumptions.	ECHA-S, MS and Committees	Completed
Carry out sensitivity analysis to identify the impact of most critical assumptions.	ECHA-S and MS	Completed
Use the public consultation for verifying key data and validating the assumptions.	ECHA-S, MS and Committees	Completed
ECHA to assist DS with gathering information on health and environment impacts during the Dossier Preparation stage starting during the PRIM and specifically when co-operating on any call for evidence.	ECHA-S	Completed
ECHA should set up an expert group to discuss improved ways of dealing with health and environment impacts including the benefit analysis	ECHA-S	Completed

6	Technicalities (Annex XV format, guidance)	
Key observations:		
• Possible revision needed for the template of the opinions, Annex XV format and guidance including SEA guidance (arising from previous recommendations). • Inconsistencies in Annex XV format make using it cumbersome. • Due to work load, only Rapporteurs likely to have read/assessed Annex XV dossier at conformity check. • Conformity check template fit for purpose given the improved understanding of scope		
Recommendations		
Recommendation	*Action actor*	*Implementation progress?*
Review/simplify format for Annex XV report. • For example, main Dossier should be short (20-40 pages maximum) giving key information (such as hazard/exposure information), additional information should be given in Annexes (but is still considered part of the Annex XV report). • Maintain link with Annex XV (all chapters A-G) covered in main dossier) • Consider more efficient use of chapters E and F avoiding duplication.	ECHA-S, COM and MS	Completed
Review opinion template to give more guidance for opinion production.	ECHA-S and Committees	Completed
Review conformity check document and give more guidance.	ECHA-S and Committees	Completed
Assess the need for further consideration of Annex XV and SEA guidance; consolidate additional guidance in addendums.	ECHA-S and Committees	Completed

Ensure all new guidance is accessible to the DS; consider use of summary document/qquick guides with the reference to these recommendations.	ECHA-S and Committees	Completed

2. Recommendations agreed following COM/ECHA workshop of 19-20 January 2016

Recommendations		
Recommendation	*Action actor*	*Implementation progress*
Share names of consulting companies or consultants that have helped in preparation of restriction proposals; ECHA could keep a "master list" for everybody's information.	The Dossier Submitter:	Ongoing
Share experience of Dossier Submitters who worked together in the preparation of an Annex XV dossier.		Ongoing
MS to cover impact on SMEs in Annex XV dossier, even if only qualitatively.		Completed
MS to work with ECHA and COM to look for more restriction proposals.		Ongoing
Explore if ECHA's framework contract could be used by MS or if a joint framework contract could be established for procuring support by consultants.	ECHA or the Commission or both	Completed
ECHA and Commission to work on a general approach on addressing recycling, spare parts, second hand articles and stocks in restrictions to help Stakeholders to better focus their comments in the public consultation. This should include guidance to help the Committees during the opinion making process.		Ongoing
ECHA to prepare a proposal on how to better streamline the reply to comments (RCOM), e.g. by changing the format or using a database approach, rather than MS-Word tables with embedded documents.		Ongoing
ECHA to propose how to improve the quality of comments received from stakeholders and develop a process for		Ongoing

verifying their input as difficulties remain during the opinion making process.		
ECHA to propose how to make public consultations more SME friendly.		Completed
RAC: Analyse the difficulties that RAC had in comparing the hazards or risks of alternatives and develop a general approach which is in between comparing only hazard information and full risk assessment of alternatives.	Committees	Ongoing
SEAC: How to increase clarity on what the Committee means when using the term 'proportionality' (as this seems to mean different things to different people in the context of restrictions).		Completed
SEAC: Opinions to report distributional effects etc. if information available.		Completed
Better guidance on responding to the Public Consultations should be provided to potential respondents.	ECHA	Completed.
Include from the start of the Public Consultation on the Annex XV restriction report better questions related to the cost and impact of the substances including those of the alternatives already known.		Completed
Comments received in the Public Consultation should be regularly evaluated by the Committee rapporteurs and ECHA secretariat for the need to gather further information from the respondent and to go back to the respondent as soon as possible. Where necessary, certain responses may be published earlier than 30 days.		Completed

3. Recommendations agreed following workshop of 17-18 May 2017

Key observations:		
• Overall, the work of the RETF is much appreciated, and implementation of the recommendations has been seen to deliver improvements in the restrictions process. • Main issues presenting difficulties with preparing restrictions: • lack of data on risk and costs (Industry often not coming forward with data) • lack of experience and resources in some MSs (and sometimes the necessary competences as well, e.g. SEA expertise) • Need for efficiency and avoiding regrettable substitution recognised - proper scoping of restrictions, e.g. wide scope restrictions, is one element to address this. • Conformity Check (CC) should assess if the information required by Annex XV was provided; other non-essential issues to judge the information provided should be dealt with through recommendations. • MSs experiencing failing a CC were not discouraged; some found the exchange quite useful; and all certainly will continue with the work on restrictions. • MSs are working on possible restriction proposals, mainly on groups of substances (e.g. PFAS (long and short chain lengths), substances in textiles). • Collaboration between MS or with ECHA for the preparation of the restrictions can be beneficial but still differences in opinion can occur and need to be dealt with. • Experts who know industry sectors very well can also be called to help. • Burden of process - no specific issues in restrictions, but compared to other risk management measures, it implies more work for MSs. In addition, competing priorities with other REACH and non-REACH processes is an issue.		
Recommendations		
Recommendation	*Action actor*	*Implementation progress*
ECHA, COM, MSCA and Committees should explore better ways of engaging stakeholders during the PC, such as through a stakeholder meeting early in the process.	All	Under consideration
Dossier Submitters are recommended to actively contact and consult stakeholders	Dossier Submitters	Under consderation

as soon as possible during the development of the restrictions proposal, such as through a dedicated workshop with key stakeholders including researchers.		
The current structure of the RoI should be reviewed to encourage stakeholders to submit early information to Dossier Submitters by clarifying the need for information to motivate derogations.	ECHA-S and Dossier Submitter	Completed
To explore whether REACH registration database can provide information on alternatives for same/similar uses across different substances.		Under consideration
ECHA and MS to consider the need for market research training or other capacity building measures on market research.		Under consideration
ECHA and COM to draft guidance to help Dossier Submitters on how to best use wide scope restrictions (grouping approach, many uses), including to cover in the scope of the restriction unwanted 'alternatives', at the same time as the substance(s) in focus (avoiding regrettable substitution).	ECHA/COM	Under consideration
ECHA and COM to provide a paper to be agreed by the RETF exploring descriptions of professional use vs industrial use to inform Dossier Preparation, particularly useful for the definition of the scope.	ECHA/COM	Under consideration
ECHA, COM and MS to further discuss the preparation of a list of substances for potential restrictions. ECHA/COM to prepare the first draft to be circulated to MS. The list should provide inspiration to MS considering restrictions. Consideration should be given to making the list publicly available (with clarifications on why the substance is on the list) and request industry to update registration dossiers or submit other information for further	ECHA/COM/Dossier Submitters	Under consideration.

consideration and to remove substances where suitable evidence is received.		

Annex IV: DOSSIER SUBMITTER'S AND ECHA'S RESTRICTION TEAM'S INVOLVEMENT IN THE RESTRICTION PROCESS.

1. Background

In the context of the Restriction Efficiency Task Force (RETF) assessment, it was considered necessary to further clarify and develop the role and the involvement of the Dossier Submitter (DS) in the restriction process. The document presents the DS's role in the different steps of the restriction process and includes the relevant recommendations made by the Task Force (see in addition Annex 1). The paper will also clarify the role of the European Chemicals Agency (ECHA) Secretariat's (ECHA-S) in the process[3] (this was another recommendation of the RETF).

2. Pre-submission phase

According to REACH Regulation, an Annex XV restriction dossier can be submitted either by a Member State (MS), by ECHA on request of the Commission or by ECHA on its own initiative (article 69(2)). It is vital for planning and operational purposes that submitting MS make their intention known to the Registry of Intentions (ROI) 12 months before the dossier is to be submitted and if possible to the pre-RoI before that. If the Annex XV dossier is prepared by two MS or one MS and ECHA, one authority should be identified as having the formal role of DS; both can be indicated in the website of ECHA.

In terms of the ECHA-S, there are 2 main teams involved: a pre-submission information meeting (PRIM) team[4] will be appointed at the time of entry in the ROI and the Restriction Team (ECHA-RT)[5] is normally appointed 4 months before the submission of the Dossier.

ECHA will offer potential DSs the opportunity to discuss their prospective restriction 6-9 months in advance of the formal submission of the dossier, either in the form of a PRIM or by providing comments on the draft dossier. This is strongly recommended to all DSs and a letter will be sent to the DS to this end once a ROI entry has been made.

In addition, ECHA will offer to assist the DS with regard to collecting evidence by publicising their call for evidence on the ECHA website and in

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[3] ECHA-S' provides support for the DS and the Rapporteurs/Committees throughout the whole restriction process and the composition of the support staff changes.

[4] The PRIM team will normally be the restriction process co-ordinator, a SID expert, the potential Restriction Team Manager and a Socio-economic expert (if not the RTM). The Committees secretariat and the Forum Secretariat will also be invited to join the PRIM.

[5] The ECHA-RT consists of the Restriction Team Manager, where relevant a co-Manager, a Committees Co-ordinator and a team assistant.

the eNews. The above mentioned letter in response to the ROI entry will also repeat this offer.

In addition, specific questions from the DS (e.g. on scope) can be discussed in a forum; more general comments on the dossier itself will be facilitated using another media format e.g. Circabc. ECHA will normally also organise, once a year, a workshop for potential DSs to discuss relevant issues.

The DS as part of their preparation of the dossier[6] will consider including the key uncertainties in their dossier, possibly in a separate section of the introductory section, to include any uncertainties around the scope of the proposal.

The DS should use the 'clear scope' document endorsed by the RETF and the Enforcement guidance (in addition to consulting with their relevant Forum member) in drafting their Dossier.

3. Conformity check phase

The conformity check is a shared responsibility of ECHA's Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) Committees who work in parallel during the 30 day period as stipulated by REACH Regulation. The conformity check procedure is launched by providing the Annex XV dossier to the Committees. The Committees need to agree on the conformity of the dossier within 30 days from the Committees' receipt of the Annex XV dossier[7]. The ECHA-RT will assist in this process by providing the Rapporteurs of both Committees a 'pre-conformity' check document based on their detailed initial assessment of the dossier[8]; this is to help the Rapporteur with undertaking their assessment but does not mean the Rapporteur cannot disagree with or add additional issues. The RETFs clear scope document will aid in determining if the proposal conforms in terms of its scope.

To facilitate a potential dialogue between the Rapporteurs and the DS, through the ECHA-RT, during the conformity check period, the Dossier will be submitted 2 weeks earlier than normal[9]. The ECHA pre-conformity check will be carried out at an earlier stage and any issues raised by the Rapporteurs can be more easily clarified with the DS, facilitated by the ECHA-RT.

The DS will continue to provide a short, focussed introductory presentation on the dossier (timing to be agreed with the Chair on a case-by-case basis) to

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6 Now agreed to be 30-60 pages in length and summarising key information with additional information in appropriate Annexes.

7 Working procedure for RAC and SEAC on conformity check of Annex XV restriction dossiers (agreed at RAC-14 and SEAC-9)

8 Only for MS dossiers

9 It is proposed to implement this starting from the 2015 Submission dates.

RAC and SEAC members during the plenary meetings where the outcome of the conformity check on the specific dossier is to be agreed. The DS representatives will follow the discussion as observers (either at the meeting or through WebEx); they are not expected to actively defend the dossier as any discussion with the rapporteurs will already have taken place. DS may be given the floor to make relevant clarifications regarding the dossier at the discretion of the Chair.

If the Annex XV restriction dossier is found to be in conformity according to both RAC and SEAC, the Secretariat informs the DS about the outcome and launches the six month public consultation on the restriction report. If there are recommendations for improvement of the Annex XV dossier by the Rapporteurs, these should be prioritised by the Rapporteurs assisted by the ECHA-RT, at the latest just after the relevant RAC/SEAC meeting[10]. The priority recommendations may, where relevant, be used as the basis of specific questions for the public consultation. These questions should be agreed between the rapporteur and the DS to ensure information is gathered that will assist with the Committees assessment of the Dossier.

If the dossier is not found to be in conformity by either or both Committees, the DS is informed of this outcome together with the detailed reasons for non-conformity. The DS is requested to bring the dossier into conformity within 60 days of the day of receipt of the reasons from the Committee(s); the ECHA-RT will be available to offer comments on a revised version of the Restriction Dossier if requested. If needed a meeting between the Rapporteurs and the DS can also be organised by the ECHA-RT; this would take place as soon as possible after the Committees have given a non-conformity opinion.

4. Opinion development phase

According to Articles 70 and 71 of the REACH Regulation, RAC shall formulate an opinion within 9 months and SEAC within 12 months from the start of public consultation on an Annex XV restriction proposal. The DS is normally involved in the restriction process as part of the Restriction Support Group (RSG: consisting of the ECHA-RT, the (co-)rapporteurs and the DS) throughout the opinion making process as they have a vested interest in the success of the dossier. The Forum secretariat or contact person may also be invited to the dialogues if requested by the Rapporteurs. It is the role of the support group to agree the input requested from the DS but in general it should be the aim of the process to limit additional information/assessment requested from the DS to the beginning of the process (this does not preclude an agreement between the parties for additional participation at any stage of the process).

[10] The Committees may provide initial prioritisation to the rapporteurs.

The DS also has a role during the preparation of the Public Consultation in regards to the discussion on specific questions to be asked. ECHA-S will consult the Rapporteurs and the DS on potential questions.

The ECHA-RT provides support to the Rapporteurs and the Committee throughout the opinion making process in terms of:

- Additional data gathering from stakeholders/3rd parties or communication within the Committees;
- Commenting on draft Key Issue's Document and opinions;
- Preparing documents for the Rapporteurs to complete e.g. Preparing documents for the Rapporteurs to complete e.g. Response to Comments (RCOM), response to comments table on the RAC/SEAC members' comments (ORCOM) etc. and supporting the completion of these documents;
- Manage the PC and provide information to DS and Rapporteurs;
- Facilitating the dialogues and coordinating the RSG work with the revision and finalisation of the Background Document[11]; and
- At the request of the Chairs any other scientific support to the Committees;
- No legal support on developing the Annex XVII proposal is necessary but rather support for clarifications on text

a. Participation at the plenary meetings

The DS is invited to participate in RAC/SEAC meetings 'in person' as an observer when the Committees discuss, agree or adopt the relevant opinions; the presence of the DS is welcomed at the meetings, as it might make the interactions much smoother and efficient. The travel and participation expenses of the DS representatives are not reimbursed; there is also a possibility to follow the plenary discussions via a WebEx connection (even if the DS also attends the meetings).

During the plenary discussions on the opinion development, the DS can follow the discussions and provide additional clarifications regarding their dossier to RAC/SEAC members when requested or at the discretion of the Chair.

In terms of the key issues papers or opinions, the DS may be asked to comment on the documents at the request of the Rapporteurs.

Where necessary, there might be a need for ad hoc groups to discuss the specific issues regarding the opinions in the margins of the plenary meetings. The DS (and stakeholders) can be invited to these ad hoc groups on a case-by-case basis as deemed necessary by the Chairmen (after consulting the (co-)rapporteurs).

[11] See sub-section c for more details on responsibilities

b. Participation at the Rapporteurs' Dialogues

On request of the RAC and SEAC (co-)rapporteurs, the DS is invited to the (co-)rapporteurs' dialogues (this is normally the case), foreseen by the Working Procedures of RAC and SEAC, which can be up to three dialogues per restriction dossier[12]. Sometimes it can be that the (co-)rapporteurs consider holding the dialogues only among themselves (usually towards the end of the opinion development process.)

There is no limitation of the number of DS representatives attending the dialogue meetings in person at ECHA, but the participation of only one DS representative is reimbursed. Attendance by WebEx or by conference call is also supported, in particular for the final dialogue.

The RT facilitates the meeting (i.e. drafts agendas and prepares action points) and chairs the sessions if the Rapporteurs do not wish to do so themselves. By the third dialogue the Commission's view if the opinions are fit-for-purpose should have been sought.

c. Input to the process related documents such as Background document, response to comments etc.

The DS as part of the Restriction Support Group (RSG: consisting of the ECHA-RT, the (co-)rapporteurs and the DS) provides input to the process related documents, such as the Background Document, the relevant RCOMs and ORCOMs related to the PC and the Forum advice.

According to the current working procedure, the DS should provide input for the first version of the Background Document; this should include answering all the relevant recommendations (as agreed between the DS and the Rapporteurs). This document should be made available to the Committees together with the versions of the draft opinions to the RAC and SEAC Committees (i.e. *by week 20* of the opinion development procedure). Following this, all additional information will in general be added to the Background Document by the Rapporteur or the ECHA-RT, in the form of RAC and SEAC 'boxes', to reflect the development of the opinions. However, if further information becomes available, for example during the PC that changes the previous information in the BD, the RSG should decide who will update the BD.

Furthermore, the DS provides responses to comments (RCOM) received within the public consultation (i.e. by *week 30* of the opinion development procedure). In some cases, the DS is also asked to provide written responses to comments submitted by the Committee members during the internal

[12] Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers (agreed at RAC-28 and SEAC-22)

consultation rounds on the Annex XV dossiers or the different versions of the opinions.

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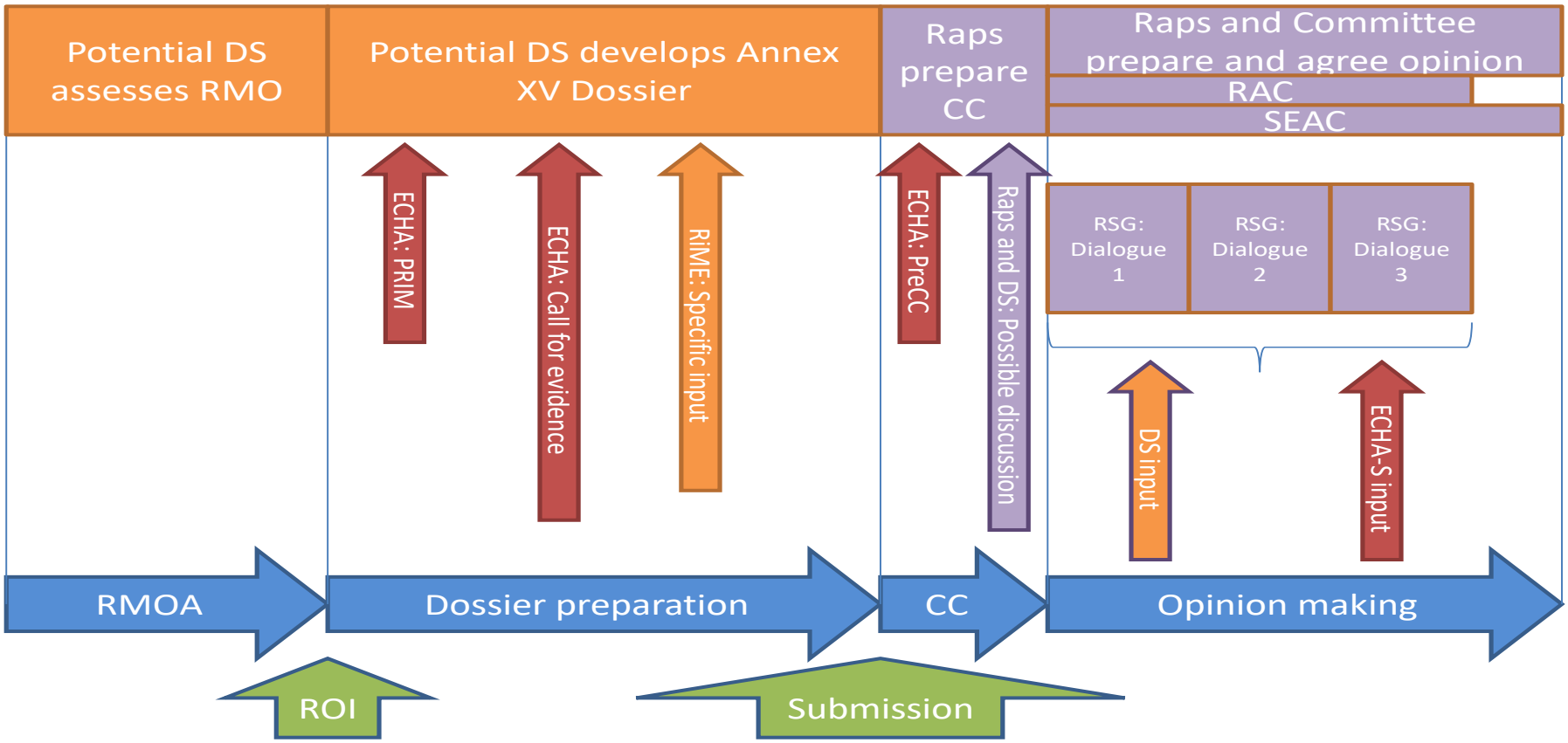
Annex 1: DS's and ECHA Secretariat's role in the different steps of the restriction process



Annex V:

RESTRICTION EFFICIENCY TASK FORCE

SETTING A CLEAR SCOPE

A common understanding for a clear scope of Annex XV restriction proposals

The scope of the Annex XV dossier is defined by the restrictions proposed in conjunction with the risk assessment performed by the dossier submitter, by the boundaries within which the assessment of risks has been performed and the analysis of the degree to which those risks are controlled.

This paper was discussed and agreed by the Restriction Efficiency Task Force (RETF) at its meeting of 8-9 October 2014.

Dossier Submitter

A. Why the DS should define a clear scope?

The boundaries of the risk assessment are determined by the dossier submitter on the basis of several considerations, including policy, and therefore do not need scientific justification; however, they need to be coherent from a scientific perspective because the scope of the Annex XV dossier in turn influences:

- **the harmonisation achieved by the restriction –** RAC will verify whether there is inadequately controlled risk and the Commission will decide whether there is unacceptable risk;
- **the efficiency of the measure –** SEAC will verify the proportionality of the measures and whether the exemptions based on socio-economic implications or lack of alternatives are well justified;
- **the possibility** for RAC and SEAC **to diverge from the restriction suggested** (within the limits of the restrictions proposed and the risk assessment provided) without having to launch a new restriction process;
- **the content of the public consultations**, which is crucial to enable all relevant stakeholders to participate in the process.

B. What are the critical elements enabling a Dossier Submitter to suggest a clearly defined restriction?

As stated in its document to CARACAL CACS/23/2013 (page 5), the Commission believes that "*In order to develop a draft restriction proposal, the Commission needs to obtain clarity on the following items:*

- *the concern to be addressed ((eco-)toxicological effect of concern, human health/environmental effect; targeted population/environmental compartment);*
- *the objective (expected outcome/benefits of the implementation of the proposed measure);*
- *the proposed measure (scope and enforcement tools, where appropriate), […]".*

Enforcement is also an additional reason for requiring a clear scope.
As far as the proposed measure is concerned, the following elements are therefore critical for defining a clear scope in the proposed restriction and should be assessed in the risk assessment in the Annex XV dossier (also presented diagrammatically in Annex I):

B. 1. Identification of substances (column 1 in Annex XVII)

The Dossier Submitter:

- should preferably provide the EC (and/or CAS) number for each substance for which a restriction is proposed;
- can propose restrictions for an entire group of substances, for instance when the identified risk relates to a common chemical structure or degradation product of the substances (e.g. "X and its compounds");
- should, when a big group is targeted, try to identify it by using the chemical formula (example: CH3)P(OH)X with X equal to F, Cl, O, etc.).

All of the substances for which a restriction is proposed should be assessed in the Annex XV dossier. If only some of them are assessed, the Dossier Submitter should justify why the results are valid for the others (justification for grouping).

B.2. Provisions (column 2 in Annex XVII)

1) Limit value for content/migration

Any limit value proposed should, for threshold substances, be based on the DNEL/PNEC or another value if justified. When there is no DNEL/PNEC, the justification for the limit should, for example, make reference to the availability/reliability of testing methods or to the limit of detection of the best performing method, if the intention is to achieve 'zero content/migration'. When both values are considered, justification should be provided to avoid two divergent values.

2) Uses

- The restriction can contain a (non-exhaustive) positive or negative list[13] of specific uses (e.g. in certain articles, type of articles, etc.);
- The restriction can target the function of one specific substance or a group of substances, e.g. flame retardants in articles supplied to the general public;
- The restriction can take the form of a total ban or a ban with exemptions;
- The restriction can be based on the substance being 'not present above a certain limit' in a specified category of articles/mixtures;
- The description of the uses or articles should relate to the target population (in terms of intended protection);
- Where relevant, the feasibility of referring to a production category should be examined (Eurostat PRODCOM Codes or CN (HS) code, or both).

3) Exemptions

- When the Dossier Submitter proposes exemptions, this must be on the basis of the risk assessment, a socio-economic assessment or other justified considerations included in the Annex XV dossier for this purpose;
- All proposed exemptions should be presented in the public consultation with the justification from Annex XV;
- All proposed exemptions must be reviewed and assessed by RAC and SEAC;
- When the exposure scenario is based on the worst case, the Dossier Submitter should clearly define any articles to be included

[13] The Annex XV Dossier should also consider this positive or negative list of articles.

in the restriction and how the extrapolation from this scenario was done for these articles and, if some articles have been excluded, suitable justification should be provided;

- The difficulties that arise when the target of the exposure scenario is a particular sub-population which is then extrapolated to a larger one need to be further discussed.

4) Conditions

- The terms "direct" or "indirect" relating to contact should be avoided unless fully described in the Annex XV dossier;
- The term 'intended for' in terms of use should be avoided (cf DCB example);
- Vague terms relating to the frequency of contact such as short, repetitive, long term, prolonged etc. should be avoided, if at all possible, as there is a need to quantify contact and even if the frequency of contact is quantified in the exposure scenario, this is difficult to enforce; moreover, if we look at the case of Nickel, ECHA took two years to provide a scientific quantification that still needs to be 'translated' into more practical guidance;
- ECHA should provide mini-guidance on the general principles of certain methodologies, with a list of examples dealt with so far by RAC (e.g. phthalates and lead for "mouthing time");
- "Normal and reasonably foreseeable conditions of use";
- Misuse: if targeted by the Dossier Submitter, may exceptionally be considered in the Annex XV dossier if it relates to known or reasonably foreseeable exposure and creates concern for human health or the environment to be addressed at Union level, and there is no other appropriate EU legislation to tackle the problem.

RAC and SEAC

A. Question from the conformity check template: "Does the Annex XV dossier specify the scope of the restriction proposed in sufficient detail?"

In order to reply positively to this question the Rapporteur should consider that the following elements are included in the Annex XV dossier:

- All the relevant elements discussed in the previous point shall be observed (in particular the relevant elements under 'B. 1. Identification of substances' and 'B.2. Provisions');

- The risk assessment done by the Dossier Submitter concludes that control of the risks identified is either adequate or inadequate (either through RCR>1, or other methods in case of non-threshold substances);

- Exemptions (based on adequate control of risk) – any such exemptions must have been fully assessed in the risk assessment;

- Exemptions (based on socio-economic implications) – any such exemptions must be based on comprehensive socio-economic analysis (e.g. indicating severe consequences for certain sectors or society; or indicating that certain sectors/ products would be disproportionately affected; or indicating that the net costs to industry, DUs, consumer or society clearly outweigh the net benefits to human health and environment).

B. How to assess whether the scope is clear at the conformity check?

As stated in its document to CARACAL CACS/23/2013 (page 10), the Commission believes that if the scope of the suggested restriction is not clear to the ECHA Committees, then the dossier cannot be considered to be in conformity with the requirements of Annex XV[14].

The clarity of the suggested restrictions should be read within the general meaning of "the scope' as described at the beginning of this paper. The suggested restriction must be coherent with the risk assessment of the Annex XV dossier; in the case of restrictions targeted at a specific product group, it should be simple for the two Committees to verify that the proposed restriction corresponds to the risk assessment. The situation can be a bit complex for restrictions with a more general scope In this case RAC and SEAC should carefully compare the proposed restriction with the range of products covered by the risk assessment of the Annex XV dossier and check that the scope of the proposed restriction is coherent and fully assessed. If it is not the case, RAC and SEAC should not consider the dossier "in conformity" and may try to clarify this aspect with the Dossier Submitter. This is crucial before launching the public consultation in order to provide information for the public consultation which is fully in line with the scope.

C. How to consider additional risk management options within the scope proposed by the Dossier Submitter?

[14] **This issue was not agreed by all members of the RETF**.

The Dossier Submitter usually proposes the preferred option as the "suggested restriction", RAC and SEAC should evaluate other options mentioned in the Annex XV dossier in a separate or combined way and therefore all these options should be part of the public consultation so that relevant information is collected and affected stakeholders participate on time.

Unless other options are only an adaptation of the suggested restriction or come from the public consultation and are fully documented, options not included in the Annex XV dossier should not be assessed by RAC and SEAC. Such "non-assessed options" may be part of the background document (following the boxes approach), if RAC and SEAC are of the opinion that it could/would constitute the best option. It would be difficult for the Commission to further process these "non-assessed options" that were not part of the public consultation.

Annex II contains some examples of previous restrictions discussing the scope and how the scope evolved during the opinion making.

Public consultation

How to define clear the scope before launching the public consultation?

In its document CARACAL CACS/23/2013, the Commission considered the public consultation as a crucial step during the opinion making process and this has also been discussed within the task force.

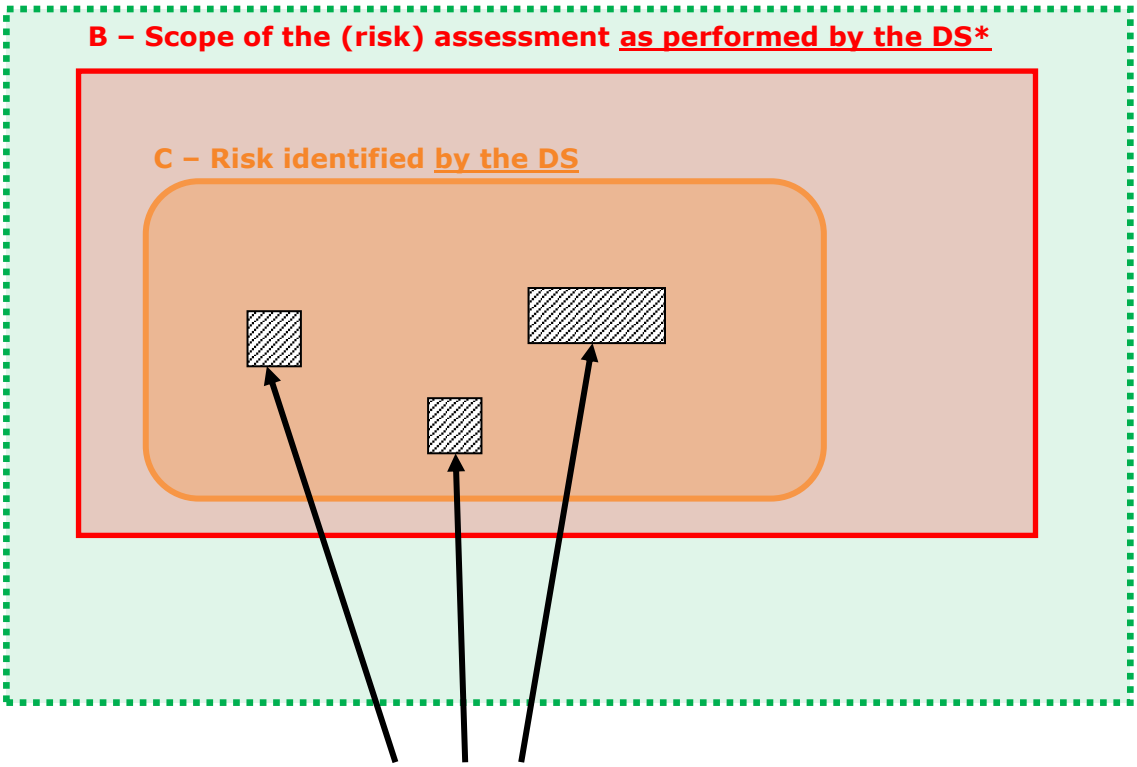
In order to obtain the right contribution from the public consultation, before launching it, there is a need to clarify the scope at the conformity check. We would like to avoid comments which are not targeting the proposed restrictions.

The proposed restriction should be part of the public consultation within the meaning of the clarification in column 1 and 2 of Annex XVII which includes conditions, exemptions, etc.

Annex I: Scope of the risk assessment and the proposed restriction as submitted by DS and assessed by RAC/SEAC

1. As submitted by DS

A – "Full scope" of assessment for the chemical substance (all uses, all exposures)

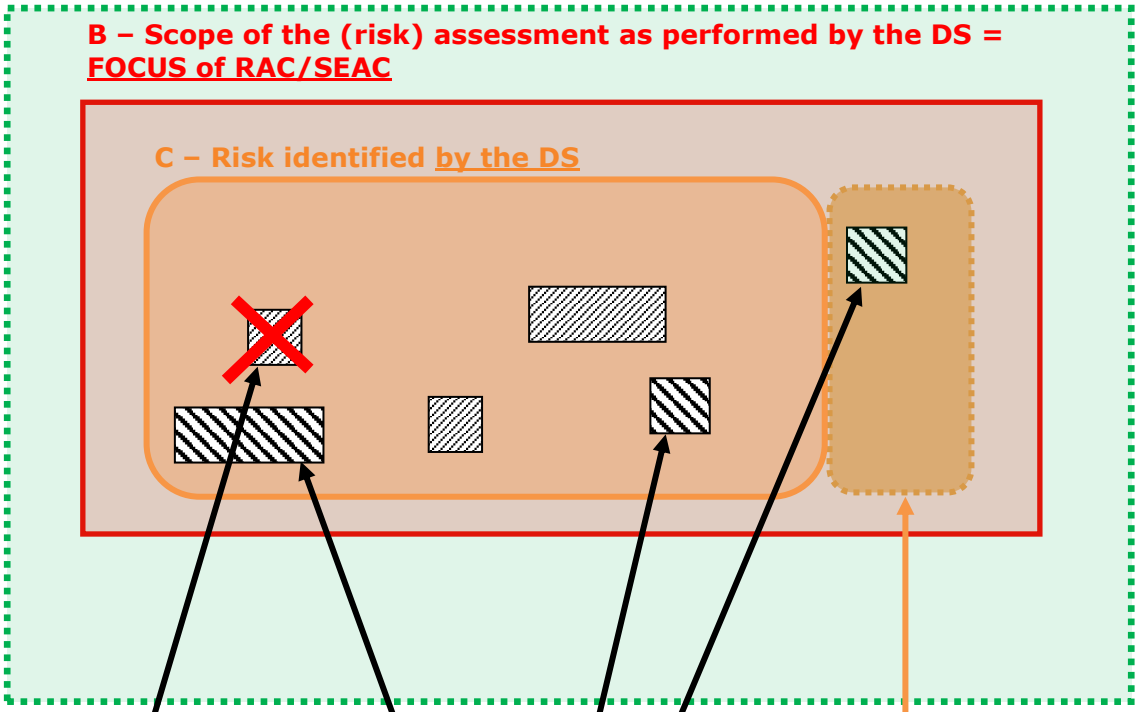


D – Exemptions based on socio-economic implications or lack of alternatives as proposed by the DS

*Exemptions based on adequate control of the risk are included in B

2. As assessed and amended by RAC/SEAC

A – "Full scope" of assessment for the chemical substance (all uses, all exposures) NOT RELEVANT for RAC/SEAC assessment



D' – Exemptions based on socio-economic implications or lack of alternatives as proposed by the DS but not supported by SEAC

C' – Additional risk as identified by RAC[1] (this includes exemptions based on adequate control risk as proposed by DS but not supported by RAC)

D'' - Exemptions based on socio-economic implications or lack of alternatives as proposed by the DS but not supported by SEAC

D – Additional/new exemptions as proposed by RAC/SEAC, including exemptions proposed during the Public Consultation and validated by RAC/SEAC

[1]: Note that RAC can express different views than the DS in both directions, i.e. either wider or narrower scope, but within the limits of the scope of the risk assessment as performed by the DS

Annex II: Examples of scope modifications/changes from previous restrictions

1. DMFu

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Dimethylfumarate Dimethyl (E)-butenedioate CAS 624-49-7 EC 210-849-0 There were no changes to the Column 1 entry from the initial proposed restriction.	1. Shall not be used in articles in concentration greater than 0.1 mg/kg. 2. Articles containing dimethylfumarate in concentration greater than 0.1 mg/kg shall not be placed on the market.	1. Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg 2. Articles or any parts thereof containing DMFu in concentrations greater than 0.1 mg/kg shall not be placed on the market	No derogations were identified in the Annex XV report. No major changes were made to the proposed restriction during the opinion making process. However, the exact wording was further clarified, e.g. to ensure that the restriction applies to all individual parts of an article.
Final proposal			
Dimethylfumarate	Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg. Articles or any parts		-

D' – Additional/new exemptions as proposed by RAC/SEAC, including exemptions proposed during the Public Consultation and validated by RAC/SEAC

[1]: Note that RAC can express different views than the DS in both directions, i.e. either wider or narrower scope, but

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Dimethyl (E)-butenedioate CAS 624-49-7 EC 210-849-0	thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market.		

2. Phenylmercury compounds

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Phenylmercury acetate (CAS 62-38-4, EC 200-532-5) Phenylmercury propionate (CAS No 103-27-5, EC No 203-094-3) Phenylmercury 2-ethylhexanoate (CAS No 13302-00-6, EC No 236-326-7)	1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures in a concentration above 0.01 % Hg weight by weight (w/w) after [5 years of the entry into force]. 2. Articles, or homogenous parts of articles, containing the substance(s) in a	RAC 1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures after 3 years of the entry into force*. 2. Articles, or parts of articles, containing the substance(s) shall not be placed on the market after 3 years of the entry into force*.	The precise wording of the restriction was changed during the opinion forming process to take into account the comments in the first and second advice from the Forum. This did not affect the scope, however. In addition, in the RAC opinion, the implementation time was changed from 5 years to 3 years. The use of phenylmercury substances was, as stated in the Annex XV restriction report, assumed to decline every year. RAC therefore was of the opinion that the sooner the restriction enters into force, the higher the impact of the restriction on reducing the global mercury pool. RAC considered, however, that a shorter phase out

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Phenylmercuric octanoate, (CAS No 13864-38-5, EC No na*) Phenylmercury neodecanoate (CAS No 26545-49-3, EC No 247-783-7) In addition RAC considered that if the five substances mentioned above were to be replaced by other organomercury compounds this restriction could become ineffective. Therefore, in addition to the conditions mentioned above, RAC recommended considering necessary	concentration above 0.01 % Hg weight by weight (w/w) shall not be placed on the market [5 years of the entry into force].	*The provisions referred to in paragraphs 1 and 2 above concerning mixtures and articles are not applicable if the concentration in a mixture or in articles or any parts thereof does not exceed 0.01 % weight by weight (w/w) mercury. SEAC 1. Shall not be manufactured, placed on the market, or used, as a substance or in mixtures after 5 years of the entry into force. 2. Articles, or parts of articles, containing the substance(s) shall not be placed on the market after 5 years of the entry into force. The provisions referred to in paragraphs 1 and 2 above concerning mixtures and articles are not applicable if the concentration in a mixture or in articles or any parts thereof	than 3 years might lead to a switch to other mercury containing alternatives. All the elements were assessed in the Annex XV report and in the two RMOs presented therin.

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
measures for verifying and controlling that other organomercury compounds (their general formula was also given)are not used as alternative to the restricted substances.		does not exceed 0.01 % weight by weight (w/w) mercury.	
Final proposal			
Phenylmercury acetate (CAS 62-38-4, EC 200-532-5) Phenylmercury propionate (CAS No 103-27-5, EC No 203-094-3) Phenylmercury 2-ethylhexanoate (CAS No 13302-00-6, EC No 236-326-7)	1. Shall not be manufactured, placed on the market or used as substances or in mixtures after 10 October 2017 if the concentration of mercury in the mixtures is equal to or greater than 0.01 % by weight. Articles or any parts thereof containing one or more of these substances shall not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0,01 % by weight.'		

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Phenylmercury octanoate, (CAS No 13864-38-5, EC No na*) Phenylmercury neodecanoate (CAS No 26545-49-3, EC No 247-783-7)			

3. 1,4-Dichlorobenzene (p-dichlorobenzene)

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
1,4-dichlorobenzene EC No. 203-400-5, CAS No. 106-46-7 The text in column 1 remained constant through the opinion making process from the original proposal	Shall not be placed on the market or used in: 1. Toilet blocks 2. Air fresheners to be used in toilets or other domestic or public indoor areas, or offices. The proposed restriction will apply 12 months after the amendment of the REACH Annex XVII comes into force.	Proposal by RAC 1. Shall not be placed on the market, or used, as a substance or constituent of mixtures in a concentration equal to or greater than 1 % by weight where the substance or the mixture is intended to be used as an air freshener or to de-odourise toilets, homes, offices and other indoor public areas. 2. Paragraph 1 shall apply from {date corresponding to 12 months after the Commission Regulation amending Annex XVII to REACH	The Forum working group on enforceability of restrictions suggested to replace the phrase "to de-odourise" with "deodoriser" to clarify that the restriction applies to air fresheners (or deodorisers) with a specific use (i.e. in toilets, homes, offices or other indoor public areas) and not e.g. to all air fresheners irrespective of their use, and the word "and" was replaced by "or" (in the phrase "or" other indoor public areas) to clarify that the phrase "indoor public areas" is not meant to include "toilets, homes and offices" but it applies in addition to those.

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
		Regulation enters into force}. Proposal by SEAC 1. Shall not be placed on the market, or used, as a substance or constituent of mixtures in a concentration equal to or greater than 1 % by weight where the substance or the mixture is intended to be used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas. 2. Paragraph 1 shall apply from {***date*** corresponding to 12 months after the Commission Regulation amending Annex XVII to REACH Regulation enters into force}. The proposed restriction should apply 12 months after the amendment of the REACH Annex XVII comes into force to	

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
		allow distributors and suppliers to sell products in stock.	
Final proposal			
1,4-dichlorobenzene EC No. 203-400-5, CAS No. 106-46-7	Shall not be placed on the market or used, as a substance or as a constituent of mixtures in a concentration equal to or greater than 1 % by weight, where the substance or the mixture is placed on the market for use or used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas.'	.	

4. Chromium VI in leather articles

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Chromium (VI) compounds IUPAC name not applicable EC number not applicable CAS number not applicable There were no changes to Column 1.	Articles or any parts thereof containing leather, coming into direct and prolonged contact with the skin, shall not be placed on the market if the leather contains chromium (VI) in concentrations equal to or higher than 3 mg/kg.	RAC • Leather articles, or leather parts of articles, coming into contact with the skin, shall not be placed on the market if they contain chromium (VI) in concentrations equal to or higher than 3 mg/kg (0,0003%) chromium VI of the total dry weight of the leather. SEAC In addition: • By way of derogation, the restriction shall not apply to leather articles placed on the market for the first time before [12 months after the amendment of the REACH	The wording of the restriction proposal was modified during the opinion forming. RAC extended the scope of the restriction, in agreement with SEAC, to cover all leather articles that come into contact with the skin. In the original proposal, only articles "in direct and prolonged contact" with the skin were covered. This change stemmed from (a) considerations on enforceability of the restriction, based on the Forum advice and (b) ECHA's on-going work on defining the "prolonged contact with the skin", which although it focuses on nickel, also evaluated corresponding scientific evidence relevant for chromium (VI).

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
		Annex XVII enters into force] • The proposed restriction will apply 12 months after the amendment of the REACH Annex XVII enters into force.	
Final proposal			
Chromium (VI) compounds IUPAC name not applicable EC number not applicable CAS number not applicable	5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0.0003 % by weight) of the total dry weight of the leather. 6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0.0003 % by weight) of the total dry weight of that leather part. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.		-

5. Lead and its compounds

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
Lead CAS No 7439-92-1 EC No 231-100-4	1. Shall not be used in jewellery articles if the	RAC Shall not be used or placed on the market in	The restriction proposal in the opinions of RAC and SEAC were different compared

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
and its compounds There were no changes to column 1	lead migration rate from such articles is greater than 0.09 µg/cm²/hr. 2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph. 3. The measure of the migration rate specified in paragraph 1 should be performed under the acidic conditions, the temperature and the duration specified in EN 71-3 standard.	. Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of the part; . The paragraph above does not apply when it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 µg/cm2/hr (0.05 µg/g per hr). SEAC 1. Shall not be used or placed on the market jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of any part of the jewellery article. 2. By way of derogation, paragraph 1 shall not apply to i) "Full lead Crystal" and "Lead Crystal" as defined in Annex I in Council Directive 69/493/EEC). ii) Precious and semiprecious stones (CN code8 7103) unless they have been treated with lead or its compounds or mixtures containing	to the original proposal by France. The proposals of RAC and SEAC also differ from each other. The original proposal proposed a migration limit and to restrict placing on the market such jewellery articles which do not conform to that limit value. The proposed migration limit value was associated with a DMEL, which was based on analytical measurement error. RAC analysed the possibility to use a content limit value as a basis for limiting lead in and considered that due to lack of validated methods for measuring migration which mimics mouthing, a restriction based on content is more practicable for implementation and enforcement. Nevertheless, and independently of the lead content, RAC considered that the restriction should not apply when it can be demonstrated that the relevant lead migration rate is not exceeded.

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
		these substances. 3. By way of derogation, paragraphs 1 shall not apply to jewellery articles placed on the market before [[12-18] months after the entry into force] and jewellery more than 50 years old on [the date specified in the restriction on cadmium].	
Final proposal			
Lead CAS No 7439-92-1 EC No 231-100-4 and its compounds	1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: a. (i) "jewellery articles" shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; b. (ii) "any individual part" shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: a. crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); b. (b) internal components of watch timepieces inaccessible to consumers; c. (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its		

Changes in column 1	Changes in column 2		
	Original scope	Changes during Committee	
		Entry	Comments
	compounds or mixtures containing these substances; d. (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961. 6. By 9 October 2017, the Commission shall re-evaluate this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.		