WSSD2020 Workshop: Collection of discussion items

General discussion items

Nr	Discussion item	Background for the item
1.	How to further **increase the integration** of REACH and CLP processes?	Further integration of CCH and SEv with RRM processes is needed in order to optimise the different processing of substances of potential concerns and to avoid delaying the identification of SVHCs and potential further regulatory actions. In particular, it should be ensured that the outcome of these processes is followed up by the development of the appropriate RRM dossiers or through actions in other areas. Moreover, where relevant, the necessary enforcement actions should be discussed as part of the overall strategy of tackling a specific problem. Another aspect to this discussion is that by trying to optimise each individual (step of a) process we may lose sight of how actions and processes are intertwined. How do we ensure that we focus on improving the overall effectiveness of the system rather than improving the individual part of it in isolation? How do we optimise the use of the parts of the REACH machinery in terms of scope and ambition level to maximise the overall outcome?
2.	How do we ensure that any measures that are proposed or taken to improve the overall outcome of the REACH/CLP machinery system do not fall back into 'old' ways of working and **respect the main paradigm change?**	REACH is based on the placing the **burden of proof** for demonstrating safe use in the industry actors. Criticism of REACH often refers to the inadequacy of the available information and the slowness of certain regulatory processes. The reaction to this is often to implement more stringent 'control' measures by authorities rather than to look for (business) incentives that could help/reward pro-active companies. This aspect also relates to some other key principles, such as **precautionary approach**, and ensuring **proportionality** in the decisions and actions by authorities. Can we improve the functioning of the REACH/CLP machinery from this perspective, i.e. allowing processes (e.g. priority setting, risk management processes) to move on even with incomplete information, encouraging and rewarding good quality information by industry, and actively discouraging the opposite, while still ensuring that actions taken respect the proportionality requirement?
3.	REACH data comprise the biggest contribution to meeting the 2020 objective of making information on chemicals available. REACH and CLP have significantly increased the knowledge about chemicals and their safe use. Are we sufficiently able to **demonstrate the benefits of the legislation?**	The EU has set an example worldwide that ambitious, overarching chemicals legislation can be made to work. This success is inspiring certain countries and regions in developing their own legal frameworks. However, other countries follow another path.

Nr	Discussion item	Background for the item
4.	Opportunities exist for better integration and collaboration between REACH and other legislation. Are there **sufficient links with other legislation** established?	Other legislation could make better use of the REACH information and instruments potentially leading to an enhanced overall efficiency. One potential area is the supply chain communication mechanism of REACH which provides companies using chemicals with a SDS (with an Exposure scenario) which contain the necessary information on the properties of substances and advice on safe use. This information can be used very effectively to fulfil specific obligations under other legislation such as worker safety, the industrial emissions or the construction products legislation and hence can provide synergies and safe resources for downstream users. It is expected that the (missing) links between CLP and other legislation form part of the fitness check of all chemicals legislation except REACH. The priority setting mechanisms for risk management measures often rely on use and exposure considerations that are covered by other EU legislation. This presents an opportunity to use the outcome of the identification of priority chemicals for setting (chemical) priorities in other legislative instruments. Has sufficient action been undertaken to ensure that REACH information is known and used of the benefit of other legislation? If not, what specific actions could be identified?
5.	How can ECHA **support third countries**, in particular developing countries in meeting the 2020 goal?	ECHA manages a huge amount of data and information which is useful for other countries in their national chemicals management. Since it can be assumed that the amount of information is not manageable and not necessary for most countries, could it be considered analysing which information is most useful for them and how that limited set of information can be made available in a convenient way (whilst respecting confidentiality and the resource constraints of ECHA)?
6.	How could **substitution of hazardous substances** with alternative substances or techniques be promoted?	Increased information due to registration and DU obligation should on its own right promote substitution, In addition REACH promotes substitution in different ways, in particular through authorisation and restrictions. Also harmonised and self-classification promote substitution. Discussions are held on how substitution could be promoted through other means (e.g. better flow of information (e.g. SubsPort), new institutional arrangements (eg. Toxics Use Reduction Act in the State of Massachusetts or industry action (eg ChemSec). Could more or other actions be taken by industry, NGOs, Member States, ECHA and the Commission to promote substitution and make better use of REACH/CLP information?
7.	Having an **understanding of the socio-economic aspects** of taking regulatory measures is often put forward as a prerequisite. Having this understanding could increase the acceptability of measures by all stakeholders and demonstrate their adequacy and proportionality.	Having an understanding of the socio-economic aspects of taking a specific regulatory action may indeed help the decision-making process. On the other hand this brings questions in which phase this information needs to be available, and at what level of detail? Moreover, how can we ensure that the process for collecting and discussing the SE aspects is transparent and that all interested parties have equal opportunities to provide their views and input both on the costs and benefits side? Another question is how to ensure that an overall (societal) view of the costs and benefits is obtained, including those of the alternative providers.

Theme 1: The extent to which registration, evaluation and any other mechanisms/instruments sufficiently ensure the availability of good quality information on uses, hazards and exposures of chemicals throughout their life-cycle

Nr	Discussion item	Background for the item
1.	**Preparations for 2018 registrations.** How to make sure that the dossier quality is improved for the low tonnage registrations.	ECHA has established, in cooperation with the MSCAs and stakeholders, the 2018 registration roadmap listing a series of actions that aim at better supporting registrants to prepare quality dossiers for 2018. The IUCLID format has been reviewed in order to help companies to better report the substance identity (incl. the scope of the substance registered jointly), use and exposure and results of studies (incl. details on the tested substance). Consequently, the automated completeness check rules have been reviewed and a manual step has been introduced to ensure that meaningful information would be provided in the dossier, hereby addressing also the level playing field. Support material and webpages are simplified and a practical guide on how to fulfil the data requirements for the 1-10 tonnes dossiers is in preparation. This will also inform on relevant alternative methods for those endpoints in order to avoid unnecessary animal testing. Communication campaigns are coordinated with the MSCAs and other bodies such as chambers of commerce. Which other actions should be recommended for ensuring compliance and quality of (future?) registration dossiers: • How to ensure that companies make use of the available tools? • How to improve the quality of the justifications where companies make use of Annex XI adaptation rules?
2.	**Dossiers compliance and quality should be improved** in order to clearly connect substance identity, hazard, use and exposure. This is a prerequisite for and interlinked with the themes – supply chain communication and regulatory risk management aspects. Although a number of actions are being put in place for low tonnages registrations of 2018, **how to best address the existing registrations**? Especially on substance identity (SID), volume and use, and hazard data? What measures could be used to **ensure the commitment of sectors to update their dossiers as**	Findings from evaluation have revealed that the registrations present a number of deficiencies both in the substance identity (SID) and the high tier environmental and human health endpoints. Registrants have extensively used adaptations to standard information requirements, including grouping approaches that often appear poorly justified and result in a significant deficiency of adequate information. Due to the sheer number of dossiers that deserve to be addressed, ECHA has established a strategy for focusing compliance checks on substances that matter most so that hazard data can be collected in priority for those substances and EU-wide risk management measures may be proposed as appropriate. Compliance check is of course an important instrument but, considering the timelines and resources needed for that process, what other actions can be recommended in order to improve dossier compliance and quality?

Nr	Discussion item	Background for the item
	currently under development for the petroleum substances (PetCo approach)?	1) Introduce an informal interaction with the registrant before starting the compliance check: • Which aspects could be addressed: SID, clarifying a justification for a category? Others? 2) More intensive dialogue Industry – ECHA – MSCA: • On specific categories of substances or certain sectors? • The PetCo approach showed first positive results; however the push was given by the fact that these substances were candidates for the SVHC roadmap. Which similar measures could be used to stimulate the commitment of sectors to regularly update their dossiers? 3) Communicate transparently: • Which substance, state of evaluation, where in process, which part of the dossier checked for compliance? • Who are the registrants concerned? 4) 'More stick, less carrots' for poor registration dossiers: • Make use of Article 5 during enforcement actions: What is needed to trigger the enforcement actions? • Continue the approach of refining the completeness check (plausibility manual checks, more detailed fields in IUCLID) that concerns 100% of the dossiers. Revocation of the registration decision in case of non-meaningful information (checked at completeness check) and persistent non-compliance. If the threat is not real, it has no effect. • Shame and blame: Should we use smileys or traffic lights? (noting this may only be effective if a large fraction of the dossiers is checked) 5) Promote good dossiers: • Publish more best practice examples? • Better ways to promote dossiers a with full data package? Should we indicate the level of waiving? i.e. *** no waiving, * extensive waiving. (noting that one star could still be in full compliance though)
3.	**Specific aspect of dossier quality: Substance identity (SID).** SID is essential information for the substances already registered for which there is a need for clarity and a link to the hazard data. For the newcomers it is important that SID is correct to ensure that they join the correct SIEF and that the hazard data of the lead dossier is suitable for their substance. (a) How to ensure that registrants construct a hazard	(a) The Substance Identification Profile (SIP) consists of the SID criteria (such as the identity of constituents and their concentration ranges) established by registrants to find out whether the dataset submitted for a registered substance applies to a composition thereof. With the new versions of IUCLID and REACH-IT in 2016, registrants will be able to report the SIP in their dossiers. Will the SID criteria of the SIP alone bring sufficient transparency on the appropriateness of the dataset to describe the properties of a registered substance? Would further transparency on the scientific rationale as to why the submitted dataset represents

Nr	Discussion item	Background for the item
	dataset that takes full account of the variability in the compositions covered by the registration? (b) How to balance the need for raising the overall quality of the SID information in registration dossiers against the focus given to the substances that matter most?	the properties of any composition meeting the SIP criteria be necessary? How can this information be best collected from the registrants? (b) One can argue that, unless registrants identify their substances to the required level of detail, they do not necessarily have sufficient knowledge to ensure that the submitted datasets are representative of their actual properties. In return, Authorities may in the worst case not have proper information at hand to best prioritise the substances to be evaluated or further regulated. What would be the most impactful action ECHA can take to ensure that the quality of the SID information for the substances that matter most is improved? To act on the highest possible number of registrations before any screening activity as part of the common screening approach? Or to act on the registrations prioritised as part of the screening? Furthermore, whenever the SID information in a registration dossier is revised, the corresponding dataset would eventually need to be reconsidered to take into account the new SID information. From experience however, registrants have typically not adapted the dataset when revising the SID in their dossiers. How to ensure that registrants reconsider the relevance of the dataset when the identity of the registered substance is not sufficiently known? Should ECHA systematically challenge the relevance of the selection of the information submitted jointly whenever requesting SID information?
4.	**Compliance check** is one essential instrument to raise the level quality. How to improve the impact of the process?	Compliance check is a time and resources intensive process for ECHA and the MSCAs. Nevertheless, it is the most powerful tool to ensure that registrants update their dossiers on the high tier endpoints. The overall number that can be handled per year depends on the number of factors such as the complexity of the case, the number of comments received on the case, etc. Although enforcement should be seen as a last resort when we would like to obtain (good quality) data. Still it should be clear that enforcement may step in if legal obligations, and ECHA decisions are not complied with. Can we recommend actions that would enable to reduce the efforts needed to carry out compliance checks and/or increase their impact? 1) For complex cases e.g. categories, should we introduce an informal interaction with the registrants for clarifying the approach taken before starting the formal process? 2) It is a fact that if many proposals for amendments (PfA) are sent, the time for processing a case is increased. Is there a way to reduce the PfAs? • By clarifying further ECHA approach on targeting substances that matter. What does it

Nr	Discussion item	Background for the item
		mean for compliance checks? • By clarifying the aspects that deserve MSCA scrutiny? 3) Due to the introduction of new test guidelines, and the consequent change in the REACH annexes, the gathering of information on reproductive toxicity, i.e. via request for OECD 443, has been delayed and significant gaps may still be present in 2018. The capacity of test laboratory will be a limiting factor. The design of the method may be subject to PfAs and principle discussions in the MSC and eventually with the Commission. • What is the right balance between the optimisation of the testing, the potential extra costs for companies, the related aspect of potential reduction of test animals, and the need to gather relevant information within reasonable time? • Should we aim at speeding up the process? 4) How to make the best use of MSCAs' capacity? • Since the evaluation work is a pre-requisite to further work on regulatory risk management, is it possible that volunteering MSs contribute directly to compliance check work? How can it be organised? • Ensuring an efficient process for dossiers proposed for SEv and (parallel?) CCH 5) Compliance check is an essential complement to substance evaluation in addressing substances of concern. The feeding of both processes is supported by a screening of all registered substances aimed at identifying substances that may require (regulatory) risk management. For this to happen it is necessary a close collaboration between MSCAs and ECHA starting from the screening and all along the evaluation life cycle. Access and sharing of all relevant information. • How can this collaboration and functional sharing of information can be improved?
5.	**How to keep a track record, communicate and consider the group of substances that have been deprioritised?**	The new evaluation strategy is based on a stepwise approach starting from a screening of all registered substances to a shortlist of candidates for further actions and/or investigations, to a pre-check to verify the presence of data gaps and the priority for CCH, and eventually a CCH, which is generally comprehensive of all 8 super-endpoints but can be targeted if more appropriate. After CCH the substance can be considered for regulatory risk management or de-prioritised. This process allows the mapping of registered chemicals and establishing pools of deprioritised chemicals (pre- or post CCH and for various reasons), prioritised and undergoing evaluation. This is not only functional to the definition of risk management, but also to build public confidence in the adequate knowledge and safe use of chemicals. • How to better report and communicate the outcomes of the process? • How to check the reliability of the stepwise processing? How to take into account the time dependent information on uses and new information on hazards?

Nr	Discussion item	Background for the item
6.	**Lack of sufficient volume, use and exposure information** hampers the identification and prioritisation of substances of concern? What are efficient ways to improve this situation?	It is clear from the last many years of REACH implementation that getting good information on how substances are being used and, where relevant, the related exposure information, is a real problem. Results of Substance evaluation show that registrants have difficulties to get uses information from their DUs. On the other side, the implementation of the "substances that matter most" strategy relies on reliable use and exposure information not only to identify and prioritise the substances that matter but also to deprioritise substances. Substance evaluation to an a certain extent can be used to get monitoring data (e.g. emission and exposure at the registrants' own sites) and promote information exchange with downstream users. Analogously compliance check can be used to for exposure information that is due as standard requirement. However, both evaluation processes concern a limited number of substances and are not the way to gather exposure information on extensive scale. Therefore, it would be good to get clarity on what use and exposure is needed for which decision-making step/process and identify/recommend potentially other ways for obtaining this information: 1) More extensive use of Article 36 to obtain existing exposure information from registrants and downstream users: • What are the criteria and boundaries for using this route? • Will it be enforceable? 2) Stimulate DUs to provide their use information: • How to better coordinate our efforts to promote the ENES tools (use maps)? • How to best reach the DUs (incl. article producers) until the bottom of the supply chain? 3) Companies volunteering to provide the information - they should do it mostly for their own benefit and not only upon request of the authorities: • How to motivate them? Would the option of de-prioritising them for further action help? • Through sticks? e.g. avoid being shortlisted on a regulatory list due to "false positives" or enforcement actions? • Through better education? e.g. through promotion of tools and support developed under ENES? 4) Further develop the approach by sector of use, based on their potential for exposure to humans and/or the environment, supplementary to the more hazard based starting point currently used in common screening: • Which sectors to prioritise? • How to motivate the sector associations to work with their members to clarify the

Nr	Discussion item	Background for the item
		uses/exposure? • Whom to contact: the registrants or the DUs? 5) Use external sources of information (not based on information provided by EU industry): • Can we directly prioritise a substance for Risk management based on external evidence (e.g. US-EPA exposure database) that the substance poses a concern due to its exposure potential?
7.	**The registration of certain categories of substances, in particular nanomaterials, is still very poor** and does not ensure adequate provision of information and safe use. How can we ensure gathering of adequate information in a reasonable time to avoid any drawback in development and innovation?	Registration requirements are not specific enough for nanomaterials to ensure the generation of relevant information necessary for their safe use. The amendment of REACH annexes is expected to greatly improve the situation by making the information requirements for nanomaterials explicit, and ECHA is preparing revised guidance for registration and read-across of nanomaterials. Nevertheless, there are regulatory and scientific aspects that make the safe use of nanomaterials a challenge and a potential threat to further development and innovation. Substance evaluation and compliance check have been used to pioneering the possibility to gather improved information. The application to REACH information requirements to substances in nanoform has been challenged in a number of appeals. • In consideration of the slow progress in clarifying the regulatory framework, what should be reasonable targets under REACH by 2020? • What incentives there could be for industry for more proactive approach for demonstrating safe use of nanomaterials in the current situation?

Theme 2: The extent to which the tools and methods developed for supply chain communication are effective (and in use) to ensure safe use of chemicals at company level, in particular for those chemicals that are not specifically addressed by the authorities

nr	Discussion item	Background for the item
1.	**How to increase/improve the information on uses and conditions of use** available to registrants for their safety assessment and for their extended safety data sheets? How to improve functioning of upstream communication prior to the 2018 registration deadline. Registration dossiers are the basis for supply chain communication (inter alia, CSR, ES, SDS) therefore**, by improving the compliance and quality, supply chain information will be improved.** **Quality of the information communicated in the** supply chain through Safety Data Sheets; what can be done to avoid misalignment between senders and receivers (information not understood)?	Registrants under REACH are expected to address (and hence understand) all uses in the life cycle of their substance in the safety assessment. This includes the technical nature of the uses and the conditions under which each of the uses takes place. Based on this understanding the registrant under REACH informs the authorities (via the registration) and the downstream users (via the extended safety data sheet) on which uses have been assessed and how to use the substance safely. Without having access to appropriate information on the existing the conditions of use and without using such information in his assessment the registrant is unable to do a proper job, with the consequence that i) authorities lack key information to run the REACH post-registration processes in an efficient way and ii) downstream users receive information not useful to them. Under the CSR/ES Roadmap (a joint stakeholder initiative launched by ECHA) methods, tools and standardised formats have been developed to support the flow of information from downstream to registrants. The methods and tools are ready for being implemented and used by industry. The potential role for the enforcement authorities in the supply-chain communication processes could as well be discussed here.
2.	How to **ensure** that safe use information is **being communicated from the registrant down the whole supply chain to the end-user of chemicals?** Improve availability, consistency, efficiency and relevance in translating safe use information for substances into safe use information for mixtures.	So far, hardly any outputs of the REACH exposure assessment by registrants has reached the users of mixtures via the safety data sheet system. One of the hurdles in this respect has been the lack of a ready to use methodology to link the substance related exposure scenario information to the safety data sheet for mixtures. Again, under the CSR/ES roadmap methods/tools have been worked out to support an efficient and consistent "translation" for substance related exposure scenario into safe use information for mixtures. The methods/tools are ready for implementation by industry. How can we ensure that these will be used in practice throughout all industry sectors?
3.	How to **stimulate a market demand for good quality "safe use or risk management advice"** information on substances and mixtures (i.e. REACH information)? **Can we activate downstream users, knowing they have an obligation also for chemicals safety?** Could we Target DUs and explain that there business is at risk if based on poor quality data or poor quality recommendations? Should we go for CEOs and explain business risk e.g. loss on consumer trust, brand, liability? Promote good eSDS based on DUs recommendations of usefulness.	The *extended safety data sheet* (extSDS) should be the primary means by which downstream end-users of substances (and mixtures) receive information relevant to them to manage risks from chemicals in their activities and processes. Ideally downstream users, of all sizes, should demand such information from their suppliers because EHS managers or product stewards (for articles) see its usefulness for improved risk management, • also efficiently supporting their obligations under other chemicals-related legislation, including product (article) safety and waste. • preventing risks to their business (loss on consumer trust, brand, liability)

nr	Discussion item	Background for the item
4.	Can the **dissemination of more SDS type of information** by ECHA help those M/I who prepare the CSR/ES, and ultimately downstream users?	Downstream users, including professional users, have to work with chemicals and really need language they understand, while the producers and importers are looking for that language as well. More standardisation of exposure scenarios in the SDS, as is currently under the attention of ENES, and making that available to producers, importers, SMEs and so also to downstream users might help in this. From a more completeness or compliance check point of view, authorities might check more the consistency between the SDS and the ES in it on the one hand and on the other hand the CSR, including exposure information.
5.	Looking forward, **how should a network like ENES develop** to better support the effective implementation of Roadmap products and to tackle new issues in supply chain communication?	The Exchange Network on Exposure Scenarios (ENES) first met in November 2011 as a way for stakeholders to share experience on the new REACH exposure scenario and to identify ways to improve their generation and implementation by industry. Since then, biannual meetings have taken place (typically 100-120 delegates) and a community of ca.250 contacts grown, including ECHA's ASO and Member States. Since 2013, ENES has contributed to product development under the CSR/ES Roadmap and acted as a forum for sharing concluded actions and agreed good practice.
6.	**The provisions applying to substances in articles** under REACH aim at ensuring the safe use of chemicals by Industry first, and at allowing public authorities to adopt regulatory measures when needed. How can the information on the use of substances in articles, which is still very limited, and its communication through supply chains, be improved further, to allow: • companies to develop and implement safe use recommendations, and • public authorities to get a more realistic picture of the situation and the information needed to take any necessary (regulatory) action? <u>*Overall strategy*</u>: Do we agree that substances in articles should require more attention, and become a priority for the coming years?	In general, REACH is strongly oriented to getting better information and safety advice on substances and mixtures and has relatively limited options for obtaining the necessary information on which substances are present in (imported) articles. In addition, assessment methodologies and communication tools are less well developed. The availability of this information is important for various reasons, a.o. to ensure full transparency on how SCHVs are being used and to provide a basis for taking actions on (gradually) substituting SVHCs which in itself is important to enable recycling of materials, an important issue within the circular economy discussions. The necessary tools for companies to report on substances in articles are available, and ECHA makes available on its website all received public information on substances in articles. Nevertheless, the information on use of substances in articles is still scarce from both registration dossiers and art. 7(2) notifications. <u>*In practice*</u>: 1. What can be done within current REACH framework (registration obligations, information flow obligations, restrictions)? • Which actions could be taken to raise the awareness and capacity of Industry to improve their knowledge and reporting of the use of substances in articles on the one hand, and the communication within supply chains on the other hand? • What incentives could be put in place to motivate Industry to be more pro-active? For instance, whether and how much the "carrot and stick" approach should be used (e.g. supporting the visibility of pro-active players *vs.* more enforcement)? • Should Commission/ECHA/Member States invest in increasing co-operation with third countries to improve information communication in supply chains from outside to inside EU?

nr	Discussion item	Background for the item
		This could include for instance co-operation in the OECD and UNEP, as well as with exporters to EU (e.g. China, India) and other importer countries (e.g. Canada). 2. Are there possibilities and added-value to work across the different pieces legislation? 3. Is there a need for new (legislative) tools in the longer term?

Theme 3: The extent to which the regulatory risk management processes are functioning adequately and with the right speed to address substances of concern

nr	Discussion item	Background for the item
1.	Despite the agreement on the SVHC roadmap and the implementation plan there's still **no common view on what regulatory risk management instruments (Authorisation, restriction or others) should be followed for which cases**. How can we bring about a more clear policy agreement in this area?	The implementation of the RMOA framework has supported a better understanding and integration of the different regulatory options by ECHA, Member States and the Commission, which has resulted in better identification of substances for further action. Nevertheless in discussions on specific actions to take (for instance during the RMOA discussions or the development of the recommendation for inclusion of substances in the authorisation list) substantial differences in view on the effectiveness of various instruments are apparent which hampers efficient decision-making. One key aspect is the knowledge on the alternatives for some (or all) the uses potentially covered by the regulatory action and whether from this information it can be concluded that these alternatives are or will become available in the foreseeable future. Another reoccurring theme is level of knowledge and certainty on uses, exposures and risks. "Restriction means any condition for or prohibition of the manufacture, use or placing on the market." Consequently the type and level of risk reduction achieved may vary considerably between the different restrictions. How to take this into account in the RMOA phase? When (what type of) restriction is an alternative to the authorisation requirement? What type of restrictions could be combined with authorisation requirement?
2.	Successful **completion of the goals of the SVHC Roadmap 2020**	The number of concluded RMOAs in PACT is still lower than originally expected (less than 50), and we see the tendency of MSCAs to not process further some categories of potential ELoC substances, such as skin sensitisers. The pool of potential SVHCs is therefore becoming more and more limited, and priorities on e.g. certain categories of ELoC substances are needed if we the aim is still to identify all relevant SVHCs by 2020. • Given that most (if not all) of the easily identifiable substances that can be added to the CL have been assessed, the further steps to identify new substances of concern often imply generation of further information and hence will take time (perceived to be slow) • Often there is no full validated data set to build on: comprehensive CCH missing, SEv is too labour some and too long. <u>Proposed way forward</u>: • ECHA's Screening activities are a good starting point, • Next step: evaluation of the substance (a first draft RMOA) to find out which data is required and which process most appropriate (reminding me of our first discussions). • In case of deficiencies of exposure data, no SEv, rather dialogue with companies in the frame

nr	Discussion item	Background for the item
		of a RMOA (at national level some good experiences were obtained with the national consultation process/PACT to get proper information about company specific exposure scenarios) Are there more/other options available?
3.	The number of restrictions proposals that are prepared is lower than originally projected. Why is this so, **should there be more restrictions,** and if so, what would be needed and what is its place in the overall risk management process (e.g. versus Annex XIV listing)?	The restrictions process is mature and has been streamlined, especially with the implementation of the recommendations from the RETF. However, ECHA and the Commission are still open to further changes in work practices that arise out of continuing experience with the process. Challenges obtaining necessary information, often held by industry, the resources needed for preparing the dossier and a sometimes a lack of internal expertise, especially related to SEA issues. Therefore a relatively low number of proposals surface each year, although in the last few years the number of proposals has increased. Another element is the challenge of having a common view on when restriction is the preferred tool and when authorization is (see also nr 1). Currently, if industry does not collaborate and provide the information to develop a restriction dossier in line with the Annex XV requirements the Committees rather conclude that the dossier is not in accordance or ultimately that there's no basis for a restriction. The Commission could clarify the situation that lack of information on tonnage, use, and even hazard data do not prevent that a restriction is proportionate – rather is it more likely that this is the case if real information from industry on uses does not come forward? Would this approach need further changes to the Committee RoPs (by the Management Board) on the basis of the Commission communication? How can we ensure that restrictions can be used for preventive actions? Should we always wait for the environment to be harmed or adverse effects on humans have occurred? This is particularly the case when persistent substances are currently used in low volumes for which is may be difficult to demonstrate risk today but for which problems in future may arise. Should it be discussed how to avoid non-sustainable uses even though we currently lack the ability to act as we may not be able to document a risk? Likewise, could it be further explored whether there are ways to implement the obligations for Annex XIV substances under the Article 69(2) process in an efficient manner, in particular where there is strong evidence that they are no longer used in articles and thus could be restricted without difficulty? Can article 68.2 be used for SVHCs on uses not applied for or not notified?
4.	What **additional (technical) help could ECHA offer** to Member States and applicants to prepare restrictions or applications?	Currently, ECHA produces and publishes values of health outcomes as well as "reference" dose-response functions and DNELs. It also holds "Pre-Restriction Information Sessions" and "Pre-Submission Information Sessions" with MS and applicants, respectively. Would there be additional support that ECHA could usefully provide?

nr	Discussion item	Background for the item
5.	The "**upstream" applications are vital for the functioning of the authorisation system** as a whole. By their very nature, they have been more general than "downstream" applications. What could be done to improve the situation? Could the role of those actors in the supply chain who specify the products (but do not use the substance) be strengthened to increase the information flow to the applicant?	The Application for Authorisation process has functioned well during the first two years of its operations. However, the preparation, opinion making and decisions of so-called "upstream" applications have been challenging. For the system to function better, it would be important to have a correct level of representative information in the applications but clearly the manufacturers of substances have difficulties to get detailed information from formulators and end users. Also the customers (e.g. Original Equipment Manufacturers), who establish the specifications of the products, do not have a role in the REACH regulation (as they do not "use" the substance). What more can possibly be done?
6.	Harmonised C&L is a simple though utmost important Regulatory management tool with many downstream consequences. What can be done by ECHA, MSCAs, COM to i) **increase the number of CLH dossiers** and ii) to have them on substances that matter (the impact of CLH on safe use is highest)?	The number of CLH proposals for industrial chemicals is ~ 15 / year. CLH is an effective RRM on its own right (results in direct obligations on actors), it triggers (semi-)automatically other regulatory obligations (restrictions on consumer uses, OHS, etc) and enables / facilitates authorisation and restrictions under REACH. Could ECHA play a central role , e.g. through encouraging MS and helping them compiling CLH dossiers (provided ECHA's resources are increased accordingly) or, by allowing ECHA a right of initiative (which would require amending Article 37 CLP) as during compliance check and all the screening activities they look at industry classification and therefore could be a motor in identifying good cases for harmonisation? Will REACH allow us to identify any new CMRs based on the current regulatory setting? Which smart options do we have?
7.	There's a **need to evaluate and look for options to improve the convergence of C&L notifications.**	CLP article 46 includes the obligation for notifiers with diverging classifications to find an agreement, which as such is a poorly enforceable requirement. ECHA facilitates this article through the C&L platform which is not used in practice. Could we more effectively promote agreement by highlighting disagreement on C&L in C&L inventory i.e. by traffic light indication? Despite the fact that the legal text does not mention this are there options for displaying the names of registrants/notifiers in order to bring them more easily into contact with each other?
8.	How can we ensure that the MSCAs ensure **appropriate resourcing of the Committees,** also for the future.	ECHAs committees are now well established and much effort has been put in ensuring that a sufficient number of the members are available to carry out the duties and, where needed, to ensure that the necessary knowledge and expertise is available. How do we maintain this knowledge level and to ensure knowledge transfer in case membership changes over time?