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Workshop on substance evaluation

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Executive summary

At the workshop, learning from the first year of substance evaluation (SEv) was discussed, although it was noted that it is still early in the process since the full cycle of decision-making and follow up is not yet complete. ECHA presented progress with development of the Community rolling action plan (CoRAP) update 2014-2016 and reported that a common screening strategy is being developed in ECHA.

Two Member States and two industry stakeholders presented their experiences with SEv and their future expectations. The Member States and industry representatives emphasised the importance of good interaction between industry and the evaluating Member State competent authority (eMSCA) during SEv. It was recognised that the type and level of interaction should be harmonised as far as possible to allow fair and equal treatment of registrants. To promote this, the workshop agreed to set up a working group to draft guidelines on interaction during SEv.

The role of the SEv report was discussed. The SEv report is not formally required under the REACH Regulation and is not part of the decision-making process. However, it was recognised that it gives clarity on what was evaluated and concluded. It could also increase the transparency of the SEv process for registrants and third parties.

The Member States expressed appreciation for the consistency screening of SEv draft decisions by ECHA before they were sent to registrants. ECHA emphasised that the SEv draft decision should be a stand-alone legal document with a clear link between the information request(s) and the identified concern(s). A new template was agreed by the workshop to improve the clarity of the SEv draft decisions. The workshop also discussed how to address exposure issues in the draft decision.

The interlinks between SEv and dossier evaluation (compliance check and testing proposal examination) under REACH were discussed. ECHA proposed a strategy on compliance check and testing proposal examination before SEv, and this was agreed. These REACH processes are independent and may proceed in parallel but the aim is to avoid interference and duplication of work as far as possible. ECHA intends to conduct compliance checks for all substances included in the CoRAP. However, substances included in the first two years of the CoRAP may be targeted only to the compliance check of substance identity (SID). In cases where the SEv and testing proposal examination would run in parallel, the testing proposal examination process could be suspended by ECHA, pending the conclusion of the SEv process.

The workshop discussed how to deal with structurally similar substances under SEv. Options for grouping the evaluation of structurally similar substances were discussed. It was not possible to select a solution which fitted all cases, but ECHA committed to screening for the structural similarity of substances during their selection for future CoRAPs and to monitor the evaluation of similar substances undergoing SEv.

1. Introduction

From 23 to 24 May 2013, the European Chemicals Agency (ECHA) hosted a workshop on substance evaluation (SEv). One key focus of the workshop was to discuss the lessons learnt from the first year of SEv. The aim of the workshop was to discuss and agree on:

- the functioning and organisation of the substance evaluation (SEv) process;
- how to improve the preparation and handling of outcome documents;
- the interface between SEv and other evaluation processes;
- how to handle groups of similar substances under SEv;
- the development of the next CoRAP updates.

The workshop was attended by 80 participants, including representatives from 26 Member States, members of the Member State Committee (MSC), MSC stakeholder observers (Cefic, CONCAWE, EUROMETAUX, ECETOC and European Trade Union Confederation), the Commission (DG Enterprise and Industry and DG Environment) and ECHA Secretariat.

Delegates from the Netherlands competent authority (CA) and German CA announced that any statements made during the workshop were the professional opinion of the delegates and not the opinion of their respective MSCAs.

The workshop agenda is included in Annex I. The workshop was divided into five sessions and covered the SEv process and CoRAP development.

ECHA's Executive Director welcomed participants and thanked the MSCAs for their commitment during the first year of SEv. The workshop was closed with conclusions and final remarks by ECHA's Director of Evaluation. Key outcomes and conclusions from the workshop were presented and discussed at the Ad hoc meeting of competent authorities for REACH and CLP from 2 to 3 July 2013.

2. Substance evaluation process - experience from the first year of evaluation

2.1 LESSONS LEARNT FROM THE FIRST YEAR OF SEV

Representatives from France and Germany gave presentations to share their experiences of the first round of SEv.

Dr Cécile Michel from ANSES explained that for the three substances evaluated by France in 2012, new concerns were found beyond those already identified in the CoRAP. France found the quality of the robust study summaries in the registration dossiers to be low and the rationale for the selection of key studies was often unclear. Consequently, France requested a number of full study reports. Dr Michel mentioned the need for further guidance to MSCAs on interaction with registrants. Is the lead registrant always the best first contact point? Can the eMSCA contact downstream users? What is the role of trade federations? Can the content of the draft decision be shared with registrants before it is formally issued? Dr Michel questioned the use and purpose of the SEv report and asked how to handle (late) updates of registration dossiers. These topics were all discussed in detail later in the workshop.

Guidance on how to assess environmental regional exposure from data across several registration dossiers was requested. Dr Michel advocated even better collaboration between ECHA and MSCA colleagues working on the same substance and also recommended for SEv practices between eMSCAs to be harmonised more.

Dr Mark Schwägler from BAuA presented his personal views on Germany's first year of SEv in which they evaluated five substances. Dr Schwägler felt that Germany had had good discussions and cooperation with industry during the process. Lead registrants were invited to meet with the eMSCA and for four substances they accepted the invitation. Two difficulties encountered during the process were handling updates of registration dossiers and dealing with confidentiality aspects within a SIEF. The role of the SEv reports was questioned; Dr Schwägler felt that more time should have been allocated to writing the draft decisions than preparing detailed SEv reports. Consistency screening of draft decisions by ECHA before formal submission was found to be helpful but Germany encountered problems with formal submission of the SEv aggregated IUCLID dossiers to ECHA. These topics were all discussed in detail later in the workshop.

2.1.1 Conclusions – how to improve the evaluation process

The plenary discussion focused on the lessons learnt from the first year of SEv and how to improve efficiency and share best practice.

ECHA reported that the timesheets provided by eMSCAs showed a large variation in the amount of time used for the evaluation. The timesheets are required by the ECHA Management Board in order to approve the transfer of funds to the eMSCA after the 12-month evaluation phase. The workshop also proposed to continue time recording during the subsequent steps of the process. ECHA agreed to explore how to arrange this and provide instructions to the MSCAs.

The MSCAs expressed appreciation for the supporting material provided by ECHA during various circumstances, including the workshop presentations. They proposed to have it collected and available in a structured and easily accessible site. One of the on-going ECHA initiatives in this direction is the development of the "Portal Dashboard", which will provide easy and integrated access to the relevant documentation and up to date information on various REACH and CLP processes, including SEv, to the MSCAs.

There was discussion on the targeting of SEv. ECHA emphasised that, in general, SEv should be conducted only once, unless according to Article 47 of REACH there is a change in circumstances or acquired knowledge.

The MSCAs felt that preparation of the SEv report took a lot of time compared to the SEv draft decision, which is (in most cases) the end product needed. This is discussed further in Section 3.2.

2.2 INTERACTION BETWEEN REGISTRANTS AND MSCAS

Dr Erwin Annys of Cefic presented industry's perspective on the first year of SEv, focusing on interaction between registrants and MSCAs during evaluation and registrant commenting on the draft decisions. Dr Annys emphasised that it is very early in the SEv process so the experience of SEv is very limited so far. Industry stakeholders feel that the process for the selection of substances for the CoRAP is unclear. The majority of companies do not clearly understand what the CoRAP is and what criteria are used for placing a substance onto the CoRAP. This is particularly the case for downstream users and retailers. Better communication with industry on the purpose of the CoRAP was requested. Dr Annys welcomed the inclusion of contact details for the eMSCA in the CoRAP and emphasised the importance of early interaction between eMSCAs and registrants to discuss the scope of the SEv and allow registrants to improve their dossiers if needed.

Dr Annys asked how registrants could be helped to understand the draft decision they receive since it can be hard to understand the legal language. If the SEv report could be shared with registrants, it may be very helpful but confidentiality issues between registrants need to be addressed.

Registrants are given 30 days to comment on the draft decision, as prescribed by REACH. Dr Annys noted that this is an extremely short period for multiple registrants to coordinate their comments, particularly when there are registrations handled by companies outside the EU. Finally, Dr Annys emphasised the need for a dialogue between registrants, eMSCAs and ECHA when non-conventional tests are requested in a draft decision.

These topics were all discussed in detail later in the workshop.

2.2.1 Conclusions - Interaction between the evaluating MSCA (eMSCA) and the registrants

The following conclusions were reached after the plenary discussion. The interaction between the eMSCA and registrants during evaluation was found to be important for the smooth functioning of the process. It appears that there are currently different practices among the eMSCAs. Some eMSCAs are very open to such interaction, including sharing of working documents during evaluation, whilst others have been more restrictive. Although different approaches may be justified due to specific circumstances, it was agreed that best practice and common rules should be identified to improve the quality of the interaction and create a level playing field for all MSCAs and registrants. Currently, there are no harmonised rules on sharing documentation outside the decision making process, such as the SEv report. Some eMSCAs described possible data-fishing attempts by certain companies. The eMSCAs should make sure they are dealing with the right persons and request documented confirmation of contact identity and who they represent, to avoid data-fishing and leaking of confidential business information (CBI).

The workshop agreed to establish a small working group to work on common guidelines/best practice for interaction, with the aim of preparing a proposal for the November 2013 CARACAL[1] meeting. The group

1 Meeting of competent authorities for REACH and CLP (CARACAL). Document CA/58/2013 "Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations" was provided for the meeting that took place in Brussels from 27 to 28 November 2013.

should also consider the sharing of the SEv report during the evaluation and decision-making phases. The group is led by IE and Cefic representatives and has members from NL, DE, UK, FR, DK, COM and ECHA.

ECHA agreed to provide a standard presentation or webinar to explain the basic principles of the SEv process to be used by eMSCAs in informal interaction with registrants.

2.3 LESSONS LEARNT FROM CONSISTENCY SCREENING

ECHA presented the lessons learnt from their consistency screening of SEv draft decisions prepared in 2012. Consistency screening was found to be a very useful learning process for both eMSCAs and ECHA. It was conducted for all 32 SEv draft decisions. Most draft decisions were submitted at the deadline of late December which meant a very high workload for ECHA during January.

ECHA's key observations relating to the scope of the information requests in the draft decisions were:

- concerns additional to those listed in the CoRAP should also be addressed;
- only concerns requiring an information request should be included;
- quality observations should not be included;
- information requests should aim to clarify a concern and anticipate the follow-up risk management required.

ECHA's key observations relating to drafting the information request were:

- reasoning for the request should be based on a concern (initial or new);
- request must be explicit, well-reasoned and enforceable;
- tiered testing requests are possible but a single deadline is preferable to avoid multiple follow-ups.

It was concluded that the SEv draft decision must be a self-standing document with clear justifications for information requests. An effective request starts from the concern, guides the registrants and looks at follow-up actions.

2.3.1 Conclusions – how to improve the consistency screening process

A plenary discussion followed and the following conclusions were reached. The consistency screening of draft decisions for substances evaluated in 2012 was highly appreciated by the eMSCAs. However, ECHA raised concern for the feasibility of the consistency screening for 2013 evaluations. Due to a higher number of substances listed on the CoRAP for 2013 (47), a higher number of draft decisions is expected. ECHA asked the MSCAs whether it would be possible to submit some draft decisions for consistency screening earlier than two months before the evaluation deadline. The majority of the speakers stated that this would most probably be impossible, in particular if they would have to submit the draft decision and the draft SEv report at the same time. ECHA agreed that the SEv report is not absolutely needed for consistency screening and can be submitted at a later stage. If the majority of the draft decisions come at the same time and just two months before the evaluation deadline, ECHA may have to prioritise among the draft decisions and may not be able to perform consistency screening on all of them.

3. Substance evaluation process - how to improve documentation and harmonise information requests?

3.1 DRAFT DECISION TEMPLATE

Based on the learning from the first round of evaluations in 2012, ECHA had prepared a revised template for SEv draft decisions aimed at more robust justifications for requesting information. In particular, the proposed structure of the statement of reasons would ensure a clear link between the requests and the identified concerns. From the template, it should also be clear whether the concern was an initial one from the inclusion to the CoRAP or an additional one found during evaluation. The revised template was welcomed in the workshop and agreed to be used for the on-going 2013 evaluations of 47 substances. For the currently existing draft decisions (32 substances) that have already been issued to the registrants, no changes due to new template would be made.

3.2 SUBSTANCE EVALUATION REPORT

One of the most discussed topics at the workshop was the role of the (interim) SEv report in the process. This document is not formally required under the REACH Regulation and is not part of the decision-making: the draft decision is a self-standing document. The key outcome of evaluation is not the SEv report but the possible draft decision and a conclusion about the risks and possible follow up regulatory risk management measures. However, based on the guidance on dossier and substance evaluation a template for the SEv report had been prepared by ECHA in consultation with the Member States and agreed in previous workshops. The SEv report is also a specified deliverable in the service contracts between ECHA and the eMSCAs.

MSCAs gave feedback that producing the SEv report may potentially take a lot of time. Among the participants, there were very different views on the role and purpose of the SEv report in the various stages of SEv. It may serve for information sharing and capacity building among the Member States. For the registrants, it could potentially identify how to improve their registration dossiers including the chemical safety report. For third parties, it could potentially increase transparency of the SEv process.

In view of the heavy workload and the difficulty of handling confidential business information (CBI), other confidential information (including personal data) and intellectual property rights (IPR), some MSCAs questioned the earlier decision to publish the SEv report. Others even questioned the need for developing such a report according to a specified format. MSCAs did not welcome the proposal of publishing the report on their own websites, instead of ECHA's website. On the other hand, some other MSCAs and stakeholder observers were of the opinion that the report is useful and should be published. Some advocated that even the interim SEv report should be shared with the registrants.

The workshop did not reach any conclusion on this topic, given that we still lack experience of the full cycle of the SEv process (decision-making, publication, follow-up and conclusion).

The decision taken in a previous workshop to publish the SEv report was not revoked. There are four substances evaluated in 2012 for which the eMSCA concluded the evaluation without a draft decision. For these substances, SEv reports and conclusion documents will soon have to be finalised for publication. ECHA has provided general instructions on how to prepare SEv reports and handle CBI/IPR when finalising them for publication. For the time being, ECHA intends to publish the final SEv reports for the above-mentioned four cases on its website.

The publication of the SEv report requires resources and could entail legal risks if CBI/IPR is not properly addressed in the report by the eMSCA. ECHA therefore reserves the right to re-discuss this approach at a later stage, when more experience is gained on the workload and the relation between the SEv report and conclusion document.

It had been agreed that reporting could be targeted to the identified concerns addressed in the evaluation. Other sections can be indicated as irrelevant for the evaluation. To simplify the handling of IPR, industry stakeholders suggested that at the beginning of the evaluation eMSCAs could request a prior authorisation from registrants to publish the non-CBI content of their CSRs.

Sharing the (interim) SEv report with the registrants in various stages of the evaluation will be addressed by the "Working group on interaction between eMSCAs and the Registrants". Since the SEv report is not formally required under the REACH Regulation and is a working document not part of the decision-making, ECHA currently leaves it to the discretion of the MSCAs to decide on whether to share the report with the registrants concerned.

3.3 INFORMATION REQUESTED IN DRAFT DECISIONS

In total, 173 information requests were made in the draft decisions prepared by the eMSCAs. However, it should be noted that the proposed requests may change following registrants' comments and considerations of other Member States.

TABLE 1. TYPES OF INFORMATION REQUESTS IN DRAFT DECISIONS FROM THE 2012 EVALUATIONS

Indicative distribution of requests	
Environment (intrinsic properties)	33%
Human health (intrinsic properties)	23%
Substance identity and physico-chemical properties	4%
Exposure (incl. worker, consumer, environment)	35%
CSR (incl. PBT, DNEL, PNEC, RCR)	5%

3.4 HOW TO ADDRESS EXPOSURE AND DNEL/PNEC ISSUES UNDER SEV

In the workshop, the discussion was targeted on how to address exposure and DNEL/PNEC- related issues under substance evaluation. There was an agreement to make exposure information requests precise, clear and enforceable. The decision should be formulated so that both the registrant and enforcement authority, if need be, are able to understand what is requested and how to comply with the request. The eMSCA should consider if, in principle, it is possible for the registrant to obtain the information in the supply chain.

The purpose of substance evaluation is not to impose a perfect chemical safety report on the registrant and thus the requests should not address all pitfalls in the chemical safety assessment. The requests should rather focus on issues raising a concern and for which potential risk management could be anticipated. The question of whether the registrant can provide the required information, e.g. from downstream user's sites, is one of the challenges. Specific concerns such as uses not assessed, missing exposure scenarios, assessment factors not justified, safe use not demonstrated, poor or incomplete documentation can be

identified during the SEv. Many of these exposure-related issues could be clarified within the informal interaction with the registrant and may not need a draft decision. Further discussion is needed to enhance common understanding on when (in which situations) further exposure information is needed to decide on the potential risk management follow up.

Regarding DNEL/PNECs, it was clarified that an SEv decision cannot impose certain DNEL/PNEC values on the registrant. However, if necessary (e.g. if this is not clarified in the informal interaction), the eMSCA may request a justification on the way the values have been derived in the registration dossier. If the eMSCA does not agree with the values derived by the registrant(s), the eMSCA can derive their own PNEC/DNEL value and use them in their assessment.

3.5 AGGREGATED IUCLID DATASET AND MEMBER STATE SEV IUCLID DOSSIERS

It was agreed that the aggregated IUCLID dataset will be provided to the eMSCAs at the time of adoption of the CoRAP update. During the evaluation, ECHA can also provide aggregated IUCLID datasets upon request. Furthermore, for substances undergoing evaluation, ECHA will provide reports of the dossier updates received on a monthly basis, until the 12-month deadline for evaluation.

All SEv IUCLID dossiers will be uploaded in the MSCA IUCLID database. There the (interim) SEV reports attached to the dossiers will be available to all MSCAs. All successfully submitted SEv IUCLID dossiers for substances evaluated in 2012 have already been transferred to the MSCA IUCLID database. ECHA urged all MSCAs to gain access to the database as soon as possible.

In future, Member States should consider how often they should update the SEv IUCLID dossier, so that it serves the decision-making process appropriately.

4. Interlinks between substance evaluation and other evaluation processes

Evaluation under Title VI of the REACH Regulation defines the assessment of registration dossiers (compliance check (CCH), examination of testing proposals (TPE) and substance evaluation (SEv)). These processes are independent of each other but are interlinked with regard to scope and procedure. Furthermore, these processes may run in parallel, potentially (negatively) interfere with each other and in some cases lead to unnecessary duplication of work. To avoid this and to ensure that these processes complement each other in an efficient manner, ECHA presented its ideas for a strategy on compliance checks and possible testing proposals prior to SEv. The approaches proposed were agreed.

Key elements of the agreed strategy are:

- ECHA intends to conduct CCH for all substances included in the CoRAP, except those added in the first year very late before the start of the evaluation.
- CCH is targeted only on substance identity (SID) for substances included in the first or second year of CoRAP.
- For the substances included in the third year of CoRAP, an overall CCH is conducted.
- In cases when SEv and TPE would run in parallel, the TPE process could be suspended by ECHA, pending the conclusion of the SEv process.

The workshop agreed that ECHA's Guidance on dossier evaluation and substance evaluation is outdated and could be withdrawn, given the other, up-to-date information available. Instructions and templates prepared by ECHA relating to SEv will be collected into a single repository.

5. Substance evaluation process – submission of outcome documents and further steps in the process

5.1 SUBMISSION OF OUTCOME DOCUMENTS

This topic covered the submission of and commenting on the outcome documents produced at the end of the 12-month evaluation stage. ECHA's presentation briefly reviewed the procedural steps involved and highlighted key areas that required further consideration.

The extension of the registrant's commenting period was raised for discussion, following claims by industry representatives that the official 30 days was not always sufficient to coordinate comments from multiple registrants of the same substance. The workshop concluded that the official commenting period of 30 days should be kept. However, extension of the commenting period could be granted in exceptional cases, such as when an incident caused by ECHA (e.g. unavailability of REACH-IT) affected the time available to the registrant(s) for comments. It was agreed that in such justified cases, ECHA could decide without consulting the eMSCAs on the granting of additional time (normally not exceeding seven days). This primarily concerns the situation where the draft decision is sent for the first time to the registrants for comments. Later, when the registrants are asked to comment on Member State/ECHA proposals to amend the draft decision, the possibility of giving any extension is limited by the timeline of the Member State Committee, which is fixed.

ECHA also sought views from MSCAs on the consideration of dossier updates where the registrant(s) indicated their intention to provide relevant information within a reasonable and specified time, after the commenting deadline had expired. Dossier updates cannot be taken into account after the draft decision is notified to other MSCAs (and ECHA) for proposals for amendments (PfAs). ECHA initially proposed three options for when dossier updates should be considered by the eMSCA:

1) Only when an update is submitted within the 30-day commenting period.
2) Only when an update is submitted within 60 days after receiving the draft decision.
3) Only when an update and submission deadline is agreed with the eMSCA, in advance.

The majority of speakers favoured option three whereas ECHA considered that this option entailed some legal risks, as it was not transparent and could affect the equal treatment of registrants. The workshop did not reach a general consensus on this topic; therefore, it would be submitted to the Ad hoc MSCA meeting for further discussion and possible agreement.[2]

It was noted that early interaction between the eMSCA and registrants during SEv could potentially minimise the need for a registrant to request an extension to the draft decision commenting deadline. This interaction does not include commenting on the draft decision. Commenting on the draft decision takes place only during the formal decision making process.

It was agreed that if SEv draft decisions are sent in batches, ECHA will release a news alert in advance to warn registrants about the start of the commenting period.

2 In the Ad hoc MSCA meeting in Helsinki from 2 to 3 July 2013 and in the subsequent written commenting round the following rule was agreed: The eMSCAs would consider dossier updates received before notification of the draft decision to other MSCAs and ECHA for PfAs, only if:
- the dossier update is agreed in advance with the eMSCA, and
- the dossier update is submitted within 60 days after notification of the draft decision to the registrant.

5.2 DECISION-MAKING PROCESS

ECHA gave a presentation on the further steps in the decision-making process outlining the process steps, related deadlines, roles and responsibilities under each step. ECHA stressed that it is the responsibility of the eMSCAs to decide on when to start the MSCA/ECHA consultation on a draft decision. This can only be done on a fixed date (six times per year), according to the MSC timelines. The eMSCA should plan carefully in which MSC meeting it intends to seek agreement on a draft decision, in case proposals for amendment (PfAs) are received. ECHA recommended eMSCAs to plan and book the resources needed throughout the decision-making phase (i.e. appoint experts and administrative staff needed to run the process through). The eMSCA is responsible for preparing the documents for the MSC. An expert from the MSCA is needed at the MSC to report and process the case.

Upon request of the MSCAs, ECHA agreed to provide support for keeping the deadlines within the decision-making procedure.

5.3 FOLLOW-UP ACCORDING TO ARTICLE 48

This topic covered the stages after the finalisation of substance evaluation, where the eMSCA must prepare the conclusion document in accordance with Article 48 of REACH. The workshop agreed to use the draft template of the conclusion document for those 2012 evaluations that are already concluded. ECHA highlighted that the draft template for the conclusion document takes into account elements of the RMO analysis template. However, more experience is needed on how to best combine these two documents to avoid duplication of work. It was proposed to raise the issue also at the RiME meeting.

With regard to the consultation with the other MSCAs, no clear need for consultation was raised for cases where no follow-up action is proposed. In cases where follow-up actions are proposed, there was support for consultation with other MSCAs (e.g. through CIRCABC and/or discussion in RiME meetings). The workshop did not reach a general consensus on this topic; therefore, it would be submitted to the Ad hoc MSCA meeting for further discussion and possible agreement.

Based on the workshop discussions, ECHA agreed to propose at the Ad hoc MSCA meeting that the final conclusion document is submitted to ECHA within four months of finalising SEv. The template provided by ECHA should be used to prepare this document. Any consultation with other MSCAs should occur before submission to ECHA. ECHA could provide the possibility for MSCA consultation through CIRCABC. For those cases requiring discussion in the RiME meeting, the submission deadline of the conclusion document to ECHA may require extension. ECHA aims to publish the final conclusion document within one month of receipt.[3]

5.4 RISK MANAGEMENT AFTER SEV

This topic covered the possible outcomes after SEv, the steps involved, and the use of the risk management option analysis (RMOA) tool to support the decision on the appropriate regulatory risk management route undertaken. The presentation compared the SEv conclusion document and the RMOA, highlighting that both cover similar information relating to the proposed regulatory risk management to be used to regulate the substance. It was highlighted that the different elements in support of RMO analysis (decision tree and

3 There was no firm conclusion in the Ad hoc MSCA meeting from 2 to 3 July 2013; some Member States think that the four-month deadline may be too short, however they agree that conclusions should be drawn as soon as possible. Some Member States recommended the alignment of the conclusion document with the risk management option analysis (RMOA). However, RMOA is a living document potentially containing a lot of confidential information and its publication is not foreseen. Discussions on the best approaches for fixing the procedure will continue.

template) are in the process of being updated in the context of the 2020 SVHC Roadmap. As a consequence, further consideration would be needed concerning the use of the RMOA and the SEv conclusion documents. Finally, communication on substance-related activities through the use of the existing overview table (also named ACT) was highlighted. This table helps to ensure that one substance is not under two different processes at the same time (except when justified) and it is important to keep it up to date.

5.5 STAKEHOLDER EXPECTATIONS

Two stakeholders were invited to present their expectations on the outcome of SEv.

Mr Hugo Waeterschoot from Eurometaux explained that from the initial experience, SEv is still seen by industry at this stage as a "corrective tool", and some of the addressed issues could be better covered under compliance check (e.g. substance identity, DNEL/PNEC calculation or AFs). However, industry expects that SEv will focus in future on more generic issues since ECHA intends to conduct compliance checks in advance of SEv when time allows. Examples of issues of generic concern could include assessing the impact of combined exposure and regional impact.

Industry promotes that the SEv process should be used to improve generic aspects of the registration dossiers. However, conclusions on substance evaluations are so far "substance specific".

Finding a tool to communicate the horizontal learning from SEv is a challenge for both ECHA and industry to increase the effectiveness of the process. How to maximise this learning and communication with other registrants of substances with identical concerns is still an open question.

Mr Chris Money from ExxonMobil presented ECETOC's view on the first experience with SEv. All SEv discussions should start with a meeting between the MSCA and the lead registrant/SIEF to plan when industry inputs are appropriate. The process should be made more efficient by encouraging on-going dialogue during the entire evaluation process. The discussions need to account for the obligations to SIEFs (e.g. joint CSRs require common ownership). In the first round of SEv, the intended outcome was sometimes unclear. ECETOC recommends that the draft SEv report be shared with the registrants in order to understand the underlying rationale and make evaluation findings clear and unambiguous.

The presentations from the two stakeholders were well received. ECHA committed to consider how to distil the learning from SEv.

6. CoRAP development - Grouping of substances

ECHA gave a presentation on how to deal with structurally similar substances under SEv.

Grouping the evaluation of structurally related substances brings a more efficient and consistent process. The objectives are to support the use of read-across approaches where possible and relevant; to ensure the allocation of similar substances to only one evaluating MSCA, or a few closely coordinated MSCAs; and to maximise the evaluation efficiency both for the clarification of the concern and the risk management follow up.

There are several different situations where grouping of substances for SEv may be needed. These cases are likely to require different approaches. ECHA has performed a preliminary analysis of different options. The scope of the analysis has been limited to substances closely related because of their structural similarity and the same hazard concern(s) and where read-across is already proposed by the registrant.

In brief, the options are the following:

Option 0 – Include all substances as individual entries in the CoRAP
It is the present situation, where substances are included in the CoRAP as individual entries, although they appear to be structurally-related and may allow the application of grouping approaches.

Option 1 – Include 'clusters' of similar substances as single entries in the CoRAP
Practically, this option would mean that a group of structurally-related substances form a 'cluster' that will be evaluated by one eMSCA during the same year. The CoRAP inclusion in one single entry is to indicate that it is regarded as one evaluation although it covers various substances.

Option 2 - Consider 'grouping' before inclusion in the CoRAP and select one or few representative substance(s) as CoRAP candidate(s)
This approach would require preliminary work to be performed before inclusion in the CoRAP, but would allow taking into account grouping possibilities without requiring administrative and procedural deviations from the standard evaluation of individual substances.

Following ECHA's presentation, delegates from the German and Danish CAs presented their opinions on this topic in relation to two groups of structurally-related substances already included in CoRAP, phthalates and xylenes under evaluation by these two MSCAs. The two brief presentations were then followed by a general discussion on this topic.

During the discussion, ECHA was requested to support the intelligent selection and allocation of similar substances. On the other hand, MSCAs have taken the commitment to collaborate among themselves for the optimal allocation and the coordinated evaluation of similar substances.

However, at the present moment, the MSCAs expressed reluctance on the feasibility of procedural options 1 and 2 as presented by ECHA. It was observed that:

- Option 1 means a reduction in the transfer of funds and may not allow full evaluations of each substance;
- Option 2 would require a preliminary analysis of structural similarities that would be too demanding and possibly insufficient for supporting the selection.

Therefore, two fundamental issues remain to be solved:

1) for substances aggregated in one single entry for the purpose of a grouping approach, the possibility to

perform targeted evaluations, i.e. on the concern which is addressed by the read-across, and
2) the modulation of the transfer of funds for different types of evaluation.

From the preliminary analysis and discussion with MSCAs, it seems clear that there is no "one-fits-all" solution and there is the need to assess all options on a case-by-case basis.

The following next actions were proposed and further discussed at the Ad hoc MSCA meeting:

1. In terms of coordination, ECHA will perform an intelligent analysis of structural similarity for future CoRAP selection and manual screening to highlight similar substances and to ensure the allocation of similar substances to only one evaluating MSCA, or a few closely coordinated MSCAs. The grouping will also be considered in relation to the need for grouping in the context of the SVHC 2020 Roadmap;
2. The evaluation of groups of similar substances already present in the CoRAP will be closely monitored and these cases will be used as pilot projects to assess how to better deal with groups of similar substances under SEv;
3. ECHA will consider possible proposals for options 1 and 2 either for existing or future groups of structurally-related substances that might enter the SEv process;
4. Based on the experience of the 2012 and 2013 evaluations, ECHA will analyse the need and options for modulating the transfer of funds according to different type of evaluations, including grouping approaches, for the ECHA Management Board to consider.

7. CoRAP development - Development of CoRAP 2014-2016

ECHA presented the progress in the development of the CoRAP update for the years 2014-2016.

The distribution of (potential) candidate CoRAP substances for manual screening and for the draft CoRAP was discussed. The workshop participants agreed that:

- the "first come, first served principle" should not apply,
- the online booking could start only after a period of e.g. 15 days during which the list of potential candidate CoRAP substances is published for information only, in order to allow coordination within the MSCAs,
- any double bookings should be resolved by subsequent bi- or multi-lateral agreement between the relevant MSCAs.

Learning from the experience of the first years of substance evaluation, it can be assumed that the annual target for SEv is about 50 substances per year.

8. CoRAP development - Towards a strategy for an effective CoRAP

ECHA presented a thought starter on the effectiveness of the CoRAP and SEv. It was recognised that the substance evaluation process has a complementary role with CCH and serves REACH, CLP and other regulatory risk management legislations. In order to select "good" or "right" CoRAP candidates leading to the relevant regulatory outcomes (e.g. SVHC Roadmap 2020, harmonised classification and labelling, restrictions) a common screening strategy is currently being developed in ECHA. In addition, synergies with other international assessments and research programmes had been recognised. The question was raised about how and what type of synergies with international programmes should we develop?

The indicators to monitor effectiveness of substance selection for the CoRAP and the SEv process will be developed over time.

9. Workshop conclusions

The Chairperson noted that the workshop was a very useful event for discussing and sharing the experience gained so far with SEv. The Chairperson thanked all the presenters and participants for their active contributions. ECHA intended to publish the workshop proceedings later on the ECHA website.

10. List of Abbreviations

AF	Assessment Factor
CA	Competent Authority
CARACAL	(Meeting of) Competent Authorities for REACH and CLP
CBI	Confidential Business Information
CCH	Compliance Check
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CoRAP	Community rolling Action Plan
CSR	Chemical Safety Report
DD	Draft Decision
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
eMSCA	evaluating Member State Competent Authority
IPR	Intellectual Property Rights
LR	Lead Registrant
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
PfA	Proposal for Amendment
PBT	Persistent, Bioaccumulative, Toxic
PNEC	Predicted No Effect Concentration
RCR	Risk Characterisation Ratio
RIME	Risk Management Experts (meeting)
RMO	Risk Management Option
RMOA	Risk Management Option Analysis
SEv	Substance Evaluation
SIEF	Substance Information Exchange Forum
SVHC	Substance of Very High Concern
TPE	Testing Proposal Examination

11. Annex I – Agenda

Workshop on Substance Evaluation
23-24 May 2013
ECHA Conference Centre, Annankatu 18, Helsinki, Finland

Thursday 23 May 2013 **Morning session**		
9.00	Registration	
	Setting the stage Chair: Leena Ylä-Mononen	
9.30	**1. Welcome** (10 min)	Geert Dancet
9.45	**2. Introduction** (10 min)	Leena Ylä-Mononen
	Session 1 on Substance evaluation (SEv) process Chair: Leena Ylä-Mononen	
10.00	**3. SEv process – experience from first year of evaluation** A. Lessons learned from first year of SEv (presentations on evaluation, preparation of outcome documents, interaction with registrants, etc.) (15 min each) B. Interaction between Registrants and MSCAs (experience during evaluation, commenting of the DD) (15 min)	 Cécile Michel, France Mark Schwägler, Germany Erwin Annys, CEFIC
10.45	**Discussion** (30 min)	All
11.15	**Coffee** (30 min)	
11.45	C. Lessons learned from consistency screening (25 min)	Claudio Carlon, ECHA
12.10	**Discussion** (30 min)	All
12.40	**Lunch** (60 min)	

Thursday 23 May 2013 Afternoon session		
	Session 2 on Substance evaluation (SEv) process Chair: Leena Ylä-Mononen	
13.40	**4. SEv process – how to improve documentation and harmonise information requests?** A. Information requested in draft decisions (including exposure and DNEL issues) (20 min) B. Harmonisation of draft decisions (template and development of standard text) (20 min) C. SEv report (20 min)	 Pia Korjus, ECHA Joakim Zander, ECHA Joakim Zander, ECHA Marita Luotamo, ECHA
14.40	Discussion (20min)	
15.00	Coffee (30 min)	
15.30	D. Member State view: How to address exposure under substance evaluation? (20 min) E. IUCLID dossier (aggregated datasets vs. SEv dossiers, dossier updates) (20 min)	Michal Wiecko, Germany Francois Le Goff, ECHA
16.10	**Discussion** (30 min)	
16.40	**5. Interface between SEv and dossier evaluation** (20min)	Evelin Fabjan, ECHA
17.00	**Discussion** (30 min)	
17.30	Conclusions / Wrap up	All
18.00	Get together at ECHA	Invited participants

Friday 24 May 2013 Morning session		
	Session 3 on Substance evaluation (SEv) process Chair: Leena Ylä-Mononen	
9.00	**6. SEv process – Submission of outcome documents and further steps in the process** A. How and when to submit and comment the outcome documents (15 min) B. Further steps in the process – decision-making process (15 min)	 Lee Walker, ECHA Anna-Liisa Sundquist, ECHA
9.30	**Discussion** (30 min)	All
10:00	C. Evaluation of obtained information and Follow-up according to Article 48 (Conclusion document) (15 min) D. Risk management after substance evaluation (15 min) E. Comments: Expectations of stakeholders about the outcomes (10 min each)	Beryl C. Nygreen, ECHA Chrystele Tissier, ECHA Hugo Waeterschoot, Eurometaux Chris Money, ECETOC
10.50	**Discussion** (30 min)	All
11.20	**Coffee** (30 min)	
	Session 4 on CoRAP Development Chair: Leena Ylä-Mononen	
11.50	**7. Grouping of substances** (20 min)	Giovanni Bernasconi, ECHA
12.10	**Discussion** (65 min)	All
13.15	**Lunch** (60 min)	

Friday 24 May 2013 Afternoon session		
	Session 5 on CoRAP Development Chair: Leena Ylä-Mononen	
14.15	**8. Development of CoRAP 2014-2016** (15 min) **9. Towards strategy for effective CoRAP** (15 min)	Marta Sobanska, ECHA Claudio Carlon, ECHA
14.45	**Discussion** (30min)	All
15.15	**Final discussion /** **Conclusions of the Workshop** (45 min)	All
16.00	End of the Workshop	

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