ECHA
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Substance Evaluation Workshop 2015

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Helsinki, 19-20 November 2015

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Summary

At the workshop, the experiences gained so far in substance evaluation (SEv) and ways to improve the process were discussed. The participants, representing Member States, the European Commission and accredited stakeholder organisations, agreed that SEv is an integrated part of the REACH and CLP machinery and also serves the management of risk from chemicals in other parts of EU-level legislation.

SEv is a powerful tool to generate the information necessary for regulatory risk management processes, so regulatory risk management thinking should guide the SEv process throughout.

Participants appreciated the preliminary report regarding workability, efficiency, effectiveness and transparency of SEv provided by ECHA's contractor. Suggestions for improvement resulting from the included survey were discussed and priority issues that need to be addressed were pointed out. ECHA had already been proactive in taking forward many of the suggestions from the survey.

The interplay between SEv and compliance check (CCH) was clarified, with the two processes complementing each other. Data gaps should ordinarily be addressed by CCH, preferably before starting SEv, but also in parallel if useful to shorten the time for evaluation.

Participants discussed how to smartly target SEv and how this should be considered by other Member States when submitting proposals to modify the information requests.

Participants also discussed how to implement the criteria to make effective requests under SEv. Four guiding criteria for robust decisions were defined, in agreement with the indications made by the Board of Appeal in a recent litigation. In particular, the best way of gathering information on exposure related concerns was discussed.

Participants agreed on the improvements that should be considered to make the overall SEv process leaner (and faster whenever possible) in order to have high annual throughput of substances with tangible outcomes, in particular with regard to the duration of the decision-making process and the enhanced role of ECHA in supporting Member States and drafting the (draft) decisions.

1. Aim of the workshop

Four years of experience with SEv allows some conclusions to be drawn on the progress made in establishing a well-functioning process, to review the current practice and to explore ways to improve efficiency and effectiveness as well as transparency and workability.

The aim of the workshop on substance evaluation held in ECHA on 19-20 November 2015 was to get a clear view and agreements on how to develop the Community rolling action plan (CoRAP) and substance evaluation (SEv) processes further. The workshop aimed to provide a platform for Member State competent authorities (MSCAs), the European Commission and accredited stakeholder organisations to communicate issues that require further discussion or endorsement.

Topics were selected largely based on the issues raised by stakeholders in feedback on the SEv process that had been provided directly to ECHA or in the survey of stakeholders. The survey was conducted by the contractor before the workshop for the report regarding workability, efficiency, effectiveness and transparency of SEv.

The agenda of the workshop is attached in Annex 1.

2. Participants

The workshop had 46 participants attending in person and 12 others through WEBEX. This includes 46 representatives from Member States, two of which attended as members of the Forum Working Group on Interlinks. These participants represented 23 different Member States. Other participants included three representatives from the European Commission, three representatives of accredited stakeholder organisations (two from industry and one environmental NGO), representatives from ECHA and four from the contractor.

3. Topics discussed at the workshop

3.1 Analysis: workability, efficiency, effectiveness and transparency of the substance evaluation process

The contractor Amec Foster Wheeler in association with Building Research Establishment Limited (BRE) and Peter Fisk Associates Limited (PFA) presented a summary of the information gathered and analysed during a survey conducted in mid-2015, as well as their preliminary reflections on “assessment of the current substance evaluation process under REACH”.

The work focused on how to improve workability, efficiency, effectiveness and transparency. The results were available to the workshop participants in more detail in a preliminary report provided by the contractor. The contractor’s report on “Assessment of the current substance evaluation process under REACH” is published on ECHA’s website (http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation).

3.1.1 Project survey

A survey to gather information and views from the MSCAs, MSC members, registrants, accredited observer stakeholder organisations and the European Commission was conducted in the course of this research to provide an evidence base for assessing the SEv and CoRAP processes and to identify recommendations for improvement.

The topics covered included the selection of substances to be listed in the CoRAP, evaluating MSCA (eMSCA) decisions on the need to request further information (assessment and preparing draft decisions), decision making (assessment of comments and seeking Member State Committee (MSC) agreement), follow-up evaluation and drawing conclusions, as well as interaction between the eMSCA and registrants and between registrants.

Overall, the survey led to a list of eight suggestions for improvements or further discussion.

Key results and comments from the survey responses included (amongst others):

- Inclusion in the CoRAP has regulatory added value for most substances and at least partly improves the quality of the dossiers.
- The common screening approach has enhanced the previous situation, leading to improvements mainly in the selection of substances and the transparency of the process.
- A better interplay with the process of compliance checks (CCHs) could improve the selection of CoRAP substances.
- There is a perceived lack of exposure-related data used to prioritise some of the substances for SEv.
- The timeline for commenting on the draft decision, as it is set in the legal text, is generally seen as challenging by the registrants, in particular where coordination among registrants is necessary.
- There is no simple option to address proposals for amendment (PfAs) for a completely new endpoint and deadlines for answering PfAs and amending draft decisions are short.
- There are difficulties in obtaining information on human health and/or environmental exposure, especially when cooperation from downstream users is needed.
- Among proposed indicators to assess the functioning of SEv, the number of cases where SEv triggered changes in company-level risk management and the number of proposals for regulatory risk management were the highest ranked, but it is clear that a few indicators are not sufficient and a broad range of them is needed for the purpose.

On the basis of the results and comments, the main suggestions for improvement or key discussion points and the influence that each of these has on the effectiveness, efficiency, workability and transparency of the SEv process were identified.

3.1.2 Assessment of transparency of substance evaluation

As part of the assessment of transparency, and independent of the survey, a review of the content of ECHA's website related to substance evaluation was conducted.

This was intended to address the question "Does the information available make the process transparent and understandable?" from the perspective of the expected users.

The approach taken was to map routes through the site and, for each web page encountered, to note the page content, any documents which could be accessed from the page, and links to other pages.

The content of each page was reviewed, along with a selection of the documents. Factors which might influence the route selected were considered (i.e. interest in a specific substance or interest in the SEv process itself).

Four starting points (one with two variations) were identified, and a map was produced for each of these.

The overall conclusions of the exercise were that there were no obvious gaps in the available information, and that there was no great difficulty in finding it, with the degree of difficulty depending on the starting point chosen. Some specific suggestions for improvements were made, the main ones being:

- Some content currently present in linked documents could be usefully added to the web page.
- The distinction between substance and dossier evaluation could be clearer on some pages.
- If possible, key pages should be as easy to find from all starting points.
- It would be useful to have a tab for substance evaluation on the home page (which would address the point above).

From the review of a sample of the documents, the following suggestions were made:

- Justification documents for CoRAP inclusion could include a better summary of the information considered in relation to the concern, and indicate whether this information came from the registration dossier or was introduced by the Member State.
- Decision documents could include a checklist showing all of the studies considered during the evaluation. Studies where there is a difference of opinion between the eMSCA and the registrant could be highlighted.

3.1.3 Key aspects on the effectiveness of CoRAP and substance evaluation

The contractors made more general considerations on the way to assess the effectiveness of CoRAP and SEv. A presentation was given that focused on five areas in which the effectiveness of the processes could be assessed, namely:

- Identification of risk at EU level
- Need for new information to understand hazard and risk
- Identification of the ‘reality’ of risks
- Need for new measures to control risk
- Efficiency of the process

The assessment of these areas appears to be premature based on the low number of evaluations finalised at the time (15 in total). The current outcomes on the substances for which a risk was identified at EU level, and for which new measures to control risks had been recommended, were presented.

In addition, information requests within the SEv process were used as an indication of the identification of the needs for new information to understand hazards and risk.

Some observations were presented which indicated that the process was functioning well to identify substances with risks on the basis of quite considerable further information

gathering. It was also stated that further information on exposure in draft and final decisions is an indication of the need for the identification of the 'reality of risks'. The meaning of this phrase 'reality of risks' was questioned and it was explained that it related to the difference between theoretical and actual risk. While a risk can be identified on the basis of, for example, modelling and certain control measures (while it is acknowledged that registrants must demonstrate adequate control), the reality may be that control measures are applied in different ways, for example, leading to lower exposures than those predicted by the models.

Programmes in other jurisdictions (non-EU) were considered to identify possible learning points for SEv. It was noted that there are already connections and synergies with other global programmes. For example, in the USA TSCA there is sharing of information on the prioritisation of substances within the programme, and the OECD CoCAP is already co-ordinated with the EU assessment programmes. The commercial concerns over data sharing between the programmes can be an obstacle and should be further clarified.

3.1.4 Plenary discussion

Following the contractor's presentation, the workshop participants discussed their views on the findings. It was noted that downstream users were not included in the survey and that the impact of SEv on downstream users was not part of the report. In relation to that, it was considered that it would be useful to have a mechanism to inform and facilitate the contribution of the downstream users on ongoing SEvs, beyond the information on CoRAP and evaluating Member State contacts publicly available on the ECHA website.

Regarding the decision-making phase, Member States did not feel that closed sessions in the Member State Committee should be limited and noted there were good reasons why they were necessary. It was recognised though, that registrants should be more involved in the process in later stages.

On the topic of indicators, participants commented that further work was needed. Indicators should be used as a tool, not seen as a goal and they should reflect the fact that evaluations can be different.

3.1.5 World café session

In the framework of a "World café" session during the workshop, participants were asked to consider on the basis of the interim report and plenary discussions which suggestions for actions resulting from the survey should be prioritised for implementing and why.

Participants indicated the top five suggestions that they thought should be prioritised.

The suggestion "Improve interplay with CCH: perform CCH prior to all SEv and even before including in CoRAP; could be sufficient to clarify concerns (no need for SEv)" received the most support for prioritisation from the participants.

Discussing MSCAs making PfAs for new endpoints, sending a stronger message to registrants to update dossiers once their substances are included in CoRAP, and improving tracking and follow-up of substances following screening as they enter other processes were other suggestions that were rated as high priorities by the participants.

It was noted that the ratings that participants gave, reflected the importance attached to the respective issue, not necessarily agreement with the suggestion. It was also clarified that the suggestions in the report came from the survey respondents and were not formally endorsed by the workshop. Instead they were suggestions for discussion in the

workshop to provide an indication to ECHA which of the suggestions are considered particularly useful.

3.2 Interplay between substance evaluation and compliance check

The workshop discussed how to improve the interplay between SEv and CCH.

In previous SEv rounds, CCH was often not covering the initial grounds for concern. This was because any requested information would not be available by the planned starting time of SEv, which would create inefficiencies and delays in the process. More recently, the Board of Appeal decision on case A-005-2014 indicates a limited possibility for SEv to fill data gaps for standard information requirements, which should ordinarily be done under CCH.

At the workshop, there was agreement that the two processes are strongly interrelated and complement each other, and that CCH needs to support SEv by filling standard data gaps. The workshop participants emphasised the need to avoid delays in addressing important risks.

For this purpose, the CCH would need to start as soon as possible after the manual screening to check the substance identity and the availability of standard information requirements in the initial area of concern.
The possibility to start SEv only after a comprehensive CCH would be the optimum situation. This can be possible when SEv is planned to start in about three-year's time (i.e. included in CoRAP for the third year). However, the prior CCH should not lead to postponement of SEv and consequent delays in the identification of regulatory risk management. For this reason, rather than postponing SEv, CCH and SEv can run in parallel.

In some cases, CCH can even start later to fill data gaps for standard information requirements identified by the evaluating MSCA during SEv and considered as necessary to conclude on the concern. The possibility of decisions with a dual legal basis was also mentioned and should be explored further.

To improve the interplay between CCH and SEv, a close collaboration and communication between the eMSCA and ECHA is essential from manual screening onwards to develop the best strategy, to decide on CoRAP scheduling and what to address in CCH and/or SEv.

Under these circumstances, the scope of CCH does not seem to be limiting the timeline of SEv. CCH would normally include the eight super endpoints[1] (and sensitisation, if part of the concern). ECHA may address also other endpoints under CCH, where needed for regulatory purposes and in agreement with the eMSCA. Multiple deadlines can be set in the CCH decision if useful to serve a parallel SEv.

3.3 Common screening

The workshop participants confirmed the appreciation for the common screening[2] and its strategic role in the identification of substances for SEv and for regulatory risk

[1] The eight super endpoints are: genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long term aquatic toxicity, biodegradation and bioaccumulation

[2] More information available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

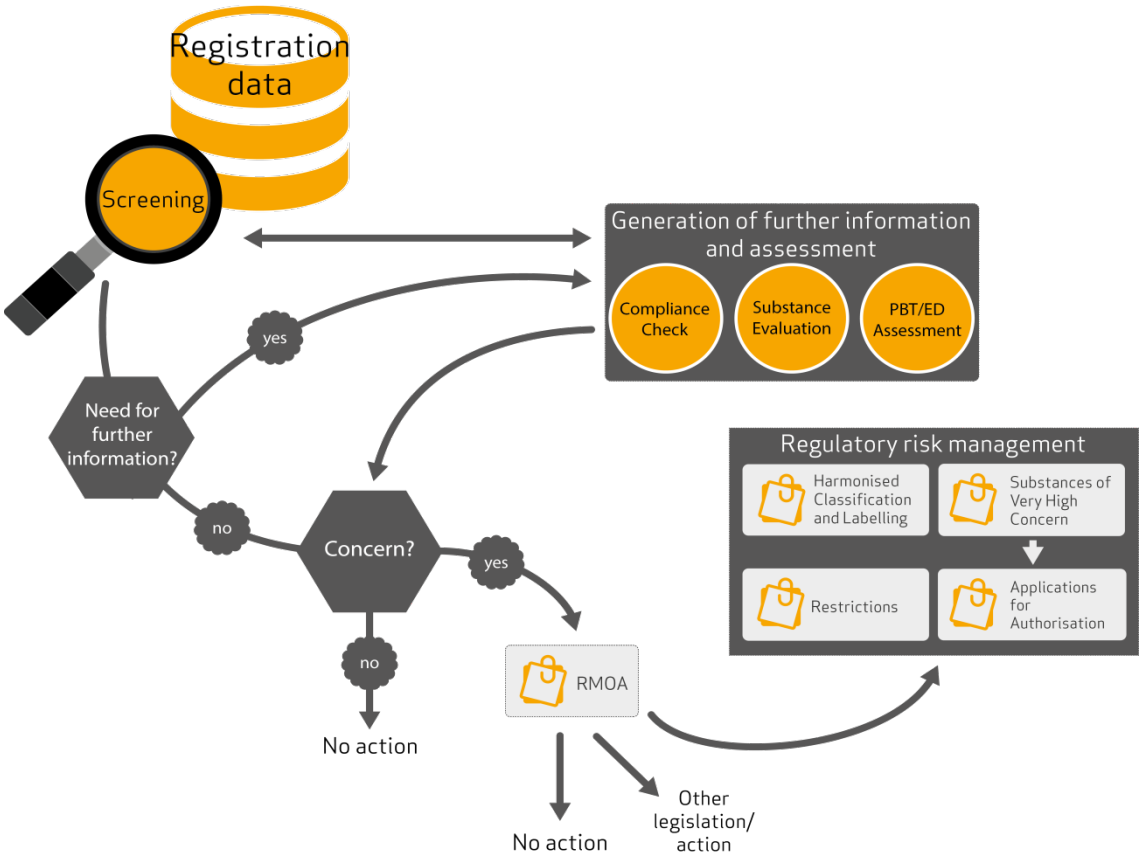
management (RRM) (Figure 1). This integration of processes will be further enhanced with the incorporation of CCH to the common screening, in line with ECHA CCH strategy endorsed in 2014[3] and to fully consider the supplementary interplay of CCH with SEv.

In the integrated process, CCH and SEv are intended to serve the generation of information necessary to ensure safe use of substances that matter, and to identify among those substances the ones requiring EU-wide regulatory risk management. Because of its strategic role, it is very important that the MSCAs continue allocating sufficient time and expertise in the manual screening of substances shortlisted by ECHA.

At the workshop, there were some calls to further broaden the scope and level of analysis during the manual screening step. However, higher ambitions would need to be balanced with the efficiency gains and feasibility of the process.

A better tracking and recording of screening results was among the top six priority recommendations in the SEv survey, to increase the efficiency and transparency of the process. The need for the quality of justification documents to be improved was also considered to ensure that the reasons for priority and appropriateness of the SEv process are clear.

Figure 1: Regulatory strategy which starts with common screening and includes CCH and SEv to generate the necessary information to conclude on the need for regulatory risk management.



[3] Available at http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

3.4 Targeting substance evaluation

The workshop discussed the principles for targeting SEv and how targeting should be considered by other Member States at the stage of submitting proposals for amendment (PfAs).

There was agreement that SEv does not aim to clarify all possible concerns, but rather to ensure adequate risk management. An intelligent targeting of the evaluation has been seen as a useful way to improve both process efficiency and effectiveness. SEv should be targeted on identified concerns based on potential regulatory follow-up. However, MSCAs stressed that where there are multiple identified concerns, it is highly uncertain which one will be eventually confirmed by test results and will lead to more severe RRM.

Therefore, targeting should be flexible and done on a case-by-case decision of the evaluating MSCA. Targeting should not lead to a situation where the same substance would be repeatedly re-evaluated because of too narrow an approach.

The workshop participants acknowledged that the capacity of a smart targeting also depends on the scope and quality of the preceding manual screening and CCH. It was considered that Member States with limited resources could possibly focus only on the most important concern and seek a partner Member State to cover the remaining endpoints, either at the start or even the during evaluation. To increase transparency, the reasons for targeting should be reflected in the justification document.

It was often observed that new concerns were raise by other MSCAs at the stage of proposals for amendment (PfAs). Addressing additional concerns under the strict timeline of the decision making was challenging and not always efficient. Therefore, the participants discussed about the possibility of limiting the scope of PfAs only to the initial scope of SEv. The imposition of such a limit was not supported. However, the inclusion of new concerns at this stage should be carefully considered and justified by anticipation of more severe regulatory follow up.

It was also felt that such additional concerns can optionally be kept on hold, or addressed by different processes (e.g. later CCH). Prior communication between the eMSCA and proposing MSCAs was encouraged as well as the development of a mechanism for early consultation among Member States.

3.5 Effective requests in substance evaluation draft decisions

3.5.1 Implementation of criteria to make effective requests

To have an efficient and effective SEv, requests for further information need to be tailor-made to obtain the information necessary to clarify the concern and to decide on the need for regulatory risk management.

Decisions should document how each request meets the criteria proposed by ECHA (pursuant to the Board of Appeal decision on appeal A-005-2014):

- Presence of potential risk as a combination of hazard and exposure information to human health or the environment that is not only theoretical;
- Necessity to clarify the risk identified (information requested tailored to real information needs);
- A realistic possibility of the requested information leading to improved risk management measures;

- Furthermore, in relation to the specific request it should be argued that the information requested is the most appropriate to address the concern, including for animal testing the absence of suitable non-animal alternatives.

At the workshop, it was discussed how to better ensure these criteria are properly considered and reflected in the decisions. ECHA proposed that a summary, e.g. in a tabular format, could be introduced either in the decisions and/or as background information in the decision making, which could help to make an analysis related to the above criteria in a concise manner. Such a tabular format would present the elements that absolutely have to be covered in a decision to explain why a certain request for further information is made under SEv.

The idea of a summary/concise table format was appreciated, but it was stressed that it should not lead to repetitions in the decision. Indeed, in the new SEv draft decision template these elements are already included as suggested subheadings for each request to be made.

It was felt that the tabular format could be useful when PfAs on new endpoints are submitted, so that both the eMSCA and registrants would be informed of the reasons for the proposal of an additional information request. It was agreed that the approach of the tabular format will be investigated further by the draft decision drafting working group.

3.5.2 Exposure requests

The workshop participants agreed that exposure requests are effective if they serve the primary objective of SEv which is to clarify the concern and decide on the need for regulatory risk management. Improving the quality of the registration dossier should not be the purpose.

Therefore, when requesting exposure information eMSCAs should keep in mind which potential follow up regulatory process (e.g. restriction, CLH or SVHC identification proposal) is intended and in which way the requested information would be used.

It was acknowledged that exposure information may be useful for confirming the level of risk and deciding on the best risk management option. For identification as an SVHC and recommendation of the substance for Annex XIV, the data required is less extensive than for restriction while exposure information is not required at all for classification and labelling proposals.

Requests of exposure should not add unnecessary administrative and assessment burdens nor should it delay the conclusion on regulatory risk management being reached. In many cases, SEv might not be the most efficient way to gather exposure information for understanding the scale of exposure. Therefore, alternative approaches should be considered and used.

Firstly, an informal contact with industry should be attempted. However, in this regard, Member States reported that registrants initially show a willingness to provide exposure information, but this is not always forthcoming, or insufficient data are provided.

The difficulty to get exposure information from downstream users (DU) was also noted. However, the draft decision adds leverage for registrants to ask for further information from downstream users so the dossier can continue to support their use. If a request on exposure in a decision is necessary, separate timelines for hazard and exposure data can be given to implement a smart testing strategy.

Another approach was to consider whether the same exposure information can be more efficiently obtained as a reaction to a regulatory risk management proposal. Additionally,

ECHA will explore the use of Article 36 letters and other means as a further way to obtain exposure information instead of requesting them in the SEv decision.

In summary, although exposure information may be requested under SEv, this may be not necessary for the regulatory purpose and other means can be more effective.

3.6 A leaner and faster substance evaluation process

The workshop discussed what improvements should be considered to make the SEv process overall leaner (and faster whenever possible) and to have high annual throughput of substances with tangible outcomes. To reach this aim, the duration of the decision making and the enhanced support of ECHA in drafting the decision at different stages during the decision-making process were discussed.

3.6.1 Faster decision making

In terms of duration of the decision-making process, it was agreed that reducing the overall duration of the SEv life cycle is essential to improve efficiency, for meeting the legitimate expectations of the registrants and to achieve the 2020 risk management goals.

ECHA noted that there has been a decreasing trend in the number of substances which were notified for PfAs within six months from the registrants' commenting period.

The eMSCAs indicated some causes for the delays: dossier updates, interaction with the registrants, and waiting for new information when agreed with the registrants. The majority of Member States was in favour of speeding up the process. However, it was felt that it is better to delay in case relevant information is known to become available. Member States considered that it is good to introduce deadlines in the process, but some flexibility is needed. The time boundaries for notifying the draft decisions for PfAs by the Member States were agreed as follows:

- within six months of the registrants comments, the eMSCA should communicate the target date for the referral of the draft decision for PfAs;
- the referral of the draft decision for PfAs should be within 12 months of the registrants' comments, otherwise the delay should be duly justified.

This should provide more transparency for the registrants about the timings of decision-making. It was also proposed that the eMSCA should inform the registrants of the substance when the draft decision is notified for PfAs.

3.6.2 Enhanced support of ECHA in drafting

Another issue for discussion in the workshop was whether it is desirable and possible to strengthen ECHA Secretariat's role in the drafting and amending the decision in the decision-making process.

According to Articles 45(1) and 47(2), ECHA is responsible for coordinating the SEv process and ensuring that substances on the CoRAP are evaluated as well as ensuring a harmonised approach to requests in SEv decisions.

ECHA and the Member States have established collaboration practices in the past, but at the workshop further possibilities for improving and strengthening ECHA's support to achieve a leaner SEv were explored.

There was general support for ECHA's verification of the draft decisions before the notification of the draft decision for PfAs in line with ECHA's responsibilities to ensure consistency among decisions. In the scope of the verification, ECHA would also propose improvements of the text of draft decisions.

As the review step will be resource demanding for ECHA, it is to be prioritised over consistency screening of the preliminary draft decisions. However, consistency screening in 2016 will still be highly requested to decide what to address under SEv or CCH, and it would still be valuable for less experienced Member States.

Ideas for prioritisation of substances for consistency screening were put forward, such as the prioritisation on the basis of the number of concerns addressed, number of vertebrate studies requested, or prioritisation by the MSCA itself.

The need of changes to the process to facilitate further agreement seeking in written procedure was also discussed. It was felt that agreement seeking in written procedure is working well and that clear criteria for selection of cases going for written procedure should be developed.

The workshop also discussed ECHA's proposal to enhance the role of the Agency in drafting the final decisions. The majority of the participants agreed that the Member State Committee (MSC) does not need to agree on the complete text of the decision, but only on the essential part (mainly information requested) and the wording of sensitive or controversial sections. ECHA and the eMSCA could then jointly finalise the decision after the meeting according to the MSC agreement.

Some participants expressed caution for this solution, and considered that other agreed measures, such as the verification step and the new template, should help already to improve the drafting and reduce the need of re-drafting at the MSC meeting. The practical implementation will be discussed further at the MSC.

4. Closed session

In the closed session, the CCH and SEv interplay was further discussed especially in relation to the Board of Appeal decision on case A-005-2014.

There was a general agreement on ECHA's proposal on how to deal with the current CCHs of CoRAP substances as well on the criteria set for keeping the request under SEv or starting a parallel CCH. Should a parallel CCH be needed, the SEv conclusions may have to be "suspended" i.e. put on hold to await the results from CCH.

The implications for CoRAP 2016 – 2018 were also discussed. The MSC CoRAP working group will take note of ECHA's analysis of standard data gaps for substances listed in the CoRAP for evaluation in 2016 and consider the actions to be proposed to the MSC. Running CCH and SEv in parallel is preferred to postponing SEvs, if the postponement would delay conclusions on regulatory risk management.

Practical examples of appeal cases were discussed. It was clarified that the Board of Appeal decisions are not precedents, but case-by-case decisions. It was agreed that there is a need to develop a manual of learnings from the appeal cases.

At the closed session, the new template for SEv decisions was also presented. It was agreed that the SEv draft decision working group will continue its work in particular on the generation of standard text and example approaches for decisions.

Conclusions

The discussions throughout the workshop led to agreement on several conclusions.

Regarding the aim of SEv, it was concluded that SEv is an integrated part of the REACH and CLP machinery and a powerful tool to obtain the necessary information to support regulatory risk management, especially beyond REACH standard information requirements.

In providing this information, it also serves other EU-level legislation that addresses management of risks from chemicals. Therefore, SEv has to be applied in a way that supports the purpose of risk management and the primary aim is not to improve the quality of dossiers or to fill formal data gaps.

The discussions held at the workshop clarified what changes in the overall process are necessary following the review of the SEv process and the decision of the Board of Appeal to achieve an optimal interplay between CCH and SEv, a better focus on SEV targeting, clearer decisions and a leaner and faster process.

ECHA will implement the proposals and agreements reached at the workshop. Some will require further elaboration and discussion e.g. at the MSC meetings. The contractor's report on "Assessment of the current substance evaluation process under REACH" is published on ECHA website.

Annex 1. Agenda

Workshop on Substance Evaluation

19-20 November 2015

ECHA Conference Centre, Annankatu 18, Helsinki, Finland

Thursday 19 November 2015 MEETING ROOM Guido Sacconi	
08:30	*Registration*
09:00	1. Welcome
09:15	2. Introduction – Objectives of the workshop
Session 1 Analysis: workability, efficiency, effectiveness and transparency of the substance evaluation process	
09:30	3. Introduction to the study ““Assessment of the current substance evaluation process under REACH (ECHA/2015/132 (SR25))”
10:00	4. Findings of the study on the steps of the SEv process regarding effectiveness, workability, transparency and efficiency
11:15	*Coffee break*
11:35	5. Conclusions from the survey and contractor’s suggestions for improvement
12:00	Discussion
12:30	*Lunch break*
Session 2 Vision for the future: aspiration for more effective and efficient substance evaluation process	
13:30	6. Evaluation suited for the purpose and interplay with compliance check and regulatory risk management processes
14:30	Discussion
Session 3 “World café” group discussions on improvement of efficiency, effectiveness and workability of substance evaluation	
15:30	7. Introduction to the World café session
15:35	World café discussions
17:40	End of Day 1
18:00	*Cocktail reception*

Friday 20 November 2015 MEETING ROOM Guido Sacconi	
Session 4 **Reporting back from World café**	
09:00	1. Reports from World café groups
10:30	Plenary discussion
11:00	*Coffee break*
11:15	2. Conclusions and agreement on actions to be taken
11:40	Closing of the open session
Session 5 **Appeals under substance evaluation**	
Session for authorities only	
11:45	3. ECHA perspective: Learnings from the SEv decisions subject to appeals
12:15	Member State perspective
12:45	Discussion
13:00	*Lunch break*
Session 6 **Towards better clarity in substance evaluation decisions**	
Session for authorities only	
14:00	4. Towards better transparency and clarity: New SEv draft decision template and instructions; lessons learned from the SEv draft decision working group
14:30	Discussion
15:00	Closing of the workshop
18:00	*End of the workshop*

Annex 2. List of abbreviations

BoA	Board of Appeal
CA	Competent authority
CCH	Compliance check
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic and reprotoxic
CoCAP	Cooperative Chemicals Assessment Programme
CoRAP	Community rolling action plan
DD	Draft decision
DU	Downstream user
ECHA	European Chemicals Agency
ED	Endocrine disruption
eMSCA	Evaluating Member State competent authority
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
NGO	Non-governmental organization
PBT	Persistent, bioaccumulative and toxic
PfA	Proposal for amendment
RMO	Risk management option
RMOA	Risk management option analysis
RRM	Regulatory risk management
SEv	Substance evaluation
SID	Substance identification
SVHC	Substance of very high concern
TSCA	Toxic Substances Control Act
WP	Written procedure

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