Substance Evaluation Workshop 2017
Proceedings

12 October – 13 October 2017

Disclaimer

Substance Evaluation Workshop 2017

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1. Setting of the workshop

The workshop on substance evaluation was held on 12 and 13 October 2017 at ECHA in Helsinki.

The workshop was divided into two parts. The first day was open to Member State competent authorities (MSCAs), the European Commission, ECHA, and accredited stakeholder observers of the Member State Committee to discuss substance evaluation policy and practical issues. The second day was restricted to MSCAs, the European Commission and ECHA discussing legal and litigation aspects.

The overall aims of the workshop were:

- to review the current state of play of substance evaluation (SEv) and its contribution to the integrated regulatory strategy;
- to consider ways of amplifying the outcomes and impact of SEv;
- to reinforce the collaboration between ECHA, MSCAs and the Registrants throughout the process;
- to ensure efficient interplay between dossier evaluation and other regulatory processes;
- to strengthen the follow-up evaluation and conclusion phases as well as their interface with regulatory risk management measures; and
- to discuss legal issues and learnings from appeals on SEv decisions.

The workshop was organised in plenary sessions, in which MSCAs, the European Commission and ECHA gave presentations on the topics, which were then discussed during each session.

The sessions of the first day were:

- Session 1: Substance evaluation in 2017 – Review of the progress made and how to further speed up getting the results
- Session 2: Effective interplay of evaluation processes and grouping approach
- Session 3: Substance evaluation follow-up
- Session 4: Next steps and follow-up tasks of the workshop.

After a brief session addressing the discussions from the first day, the second day focused on legal aspects and learnings from litigation cases related to SEv.

The workshop agenda is included in Annex I. Explanations of abbreviations used in this report are found in Chapter 6.

2. Participants

The workshop had 41 participants from 21 Member States (including Norway), 7 from accredited stakeholder observers (Eurometaux, UEAPME, CONCAWE, Cefic, EEB, ClientEarth, PETA), 3 participants from the European Commission services, as well as many staff members from the ECHA Secretariat. The Board of Appeal (BoA) members from ECHA participated in the first day's open sessions and partly in the second day's proceedings.

3. Background on substance evaluation

Member States evaluate certain substances to clarify whether their use poses a risk to human health or the environment. The evaluation can lead to a request of further information from the Registrants of the substance to verify the suspected concern, if necessary.

The evaluation may conclude that the risks are sufficiently under control with the measures already in place. Otherwise, it may lead to the proposal of EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH.

In cooperation with the Member States, ECHA defines risk-based criteria and then selects the substances to be evaluated. The selected substances are listed by ECHA in the Community Rolling Action Plan (CoRAP) following the opinion of the Member State Committee. An evaluating Member State is designated for each substance in the final CoRAP.

The initial reason for selecting a substance for the CoRAP does not limit the scope of the (subsequent) evaluation. During the evaluation, the evaluating Member State may identify other concerns that need clarification in order to conclude whether a substance is of concern or not. However, the Member State may focus the evaluation more upon certain aspects of the substance over others.

The substance evaluation process assesses all registration dossiers from all Registrants specific to the same substance, in order to take into account the combined exposure. Other available sources of information are also considered.

The evaluating Member State has 12 months from the publication of the CoRAP to decide whether it needs to request further information from the Registrants to clarify the concern. This request might go beyond the standard information requirements of REACH (Annexes VII to X) and may pertain to the intrinsic properties of the substance or its exposure. For example, Registrants may need to provide studies on mode of action or monitoring of concentration levels in organisms or the environment.

The view that further information is needed is shared with all the other Member States and ECHA to achieve a unanimous agreement on the draft decision prepared by the evaluating Member State. ECHA takes the decision to request for further information accordingly.

4. Topics discussed at the workshop

4.1. Substance evaluation in 2017 - Review of the progress made and how to further speed up getting the results

4.1.1. Strategic discussion

ECHA and the Member State competent authorities have developed a common screening approach to systematically screen available information for substances in the REACH registration dossiers and other databases to identify substances for the following REACH and Classification, Labelling and Packaging (CLP) regulatory processes:

- compliance check (CCh);
- Community Rolling Action Plan (CoRAP) under SEv;
- potential further regulatory risk management measures under the REACH and CLP regulations, i.e.:
    - harmonised classification and labelling
    - authorisation
    - restriction.

Consensus on the strategic importance of integration of the REACH and CLP processes and prioritisation was confirmed, as well as the objective to keep seeking for measures to speed up the process ("faster and better").

New challenges and opportunities were discussed, including:

- the addressing of substances by group – an approach which has already started to be developed for use in context of SEv by ECHA and MSCAs;
- a collaborative approach between Member States and industry (COLLA) – there are COLLA pilots ongoing and in 2018 the first outcomes of the approach can be considered;
- the economic aspects relating to Member States' use of resources across different process phases of the regulatory strategy, e.g. manual screening, COLLA, SEv, RRM.

A Commission representative triggered discussion on whether more substances should be evaluated annually within SEv. Participants representing MSCAs responded that the current number of substances in the CoRAP is partly limited by the capacity to carry out a CCh. A CCh is required to address main human health and environmental endpoints for high tonnage substances. It requires time to perform the missing higher tier studies. After this, the impact of the new information needs to be considered, as well as whether SEv is still needed. In addition, there is scarcity of resources. The MSCAs that have been more active in SEv in the past are now feeling the burden of having many open cases and follow-up evaluations of earlier cases to see to. Furthermore, MSCAs are spending more resources at the beginning of the process, in particular in the manual screening of groups of substances. The conclusion was that the overall impact is more important than increasing the number of annual evaluations.

There is a challenge related to the optimal distribution of the limited resources across REACH and CLP processes. There is an expectation that allocating more resources upstream of the processes will be beneficial. In the context of future decision making, the results of COLLA pilots in early 2018 will play an important role.

As a future outlook, it was noted that there is a need to develop a SEv strategy for low tonnage substances for which the registration deadline is in 2018, and thus there is a potential need to change the SEv prioritisation criteria accordingly.

4.1.2. Progress in substance evaluation

The benefits of using the existing measures (i.e. early interaction, consistency screening, and verification checks) for enhancing collaboration between ECHA and the evaluating MSCAs was highlighted. There was a general acknowledgement of the following successes:

- good progress and contribution by all actors – ECHA (including the BoA), evaluating MSCAs, and the Registrants;
- increased collaboration between evaluating MSCAs and ECHA secretariat – evaluating MSCAs have expressed appreciation for the support from ECHA substance managers;
- more targeted and more fit for purpose evaluations within the regulatory strategy are now performed, compared to those performed when SEv began;
- improved quality of SEv evaluations and outcome documents due to learning by doing;
- reduction in the backlog of cases in the decision making phase due to improved planning and focus on core issues.

However, it was noted that the process can be further improved by:

- speeding up the process, for example, by further reducing the time required to consider Registrant comments before referral of the draft decision to MSCAs and ECHA for commenting;
- improving the efficiency of the use of MSCAs' and ECHA's resources ECHA's service to informally verify draft decisions before they are referred to the Member States and ECHA for proposals for amendment: has proven to be very valuable; however, to benefit from this opportunity, the MSCAs would have to regularly plan this step in their internal process in preparation of the draft decision, and consequently, in many cases MSCAs could not yet find the time to request verification prior to the referral;
- early interaction with the Registrants (e.g. collaborative approach), which has been very much appreciated by industry and appears to be a valuable way of working.

Regarding measures to speed up and make the process lighter, two specific measures were proposed:

- Sequential testing requests in one decision: Exploring how to avoid multiple decision-making rounds, for example, considering whether the approach adopted for CCh addressing both extended one generation reproductive toxicity study and related endpoints has been efficient and is applicable to other types of request under SEv.
- Faster throughput in Member State Committee decision making: Exploring the possibility to give a broader mandate to the evaluating MSCA to finalise the drafting of the justification part of the decision (with ECHA support) upon Member State Committee agreement. This should not significantly delay the issuing of the final decision to the Registrants.

4.2. Effective interplay of evaluation processes and grouping approach

4.2.1. Scope of substance evaluation and substance identity

The overall scope of SEv and the meaning of substance identity to support work on SEv was discussed. The following conclusions were reached:

- SEv is not considered to be the most appropriate route to address substance identity-related issues;
- ECHA aims to solve substance identity issues upfront in CCh, with special attention to chemical substances of unknown or variable composition, complex reaction products or biological materials (UVCB) and read-across substances, but the work will be primarily focused on SEv-related needs on the grounds of time and capacity limitations;

- SEv can be targeted and does not need to address all issues – substance identity-related issues can be left outside the scope of the evaluation if they are not related to the concern that may lead to regulatory risk management.

As further conclusions, in SEv, it was agreed to take into account the following considerations:

- the substance identity requests in the SEv decisions must be related to the concern;
- the interest of SEv lies in EU-level risk management, not company-level risk management;
- substance identity profile information is useful information for SEv, but it cannot be addressed as an information requirement;
- substance identity/substance identity profile issues can also be resolved early by informal interaction with the Registrants;
- full substance identity compliance of all the members of a joint submission, including adequate information on all components and impurities, can be addressed by means other than SEv.

4.2.2. Addressing substances by group

The term 'group' in this context is **not** limited to categories or groups meeting the criteria of REACH Annex XI, section 1.5 (grouping of substances and read-across approach). The definition of group is different at each stage of the process. Addressing substances in groups primarily means that the relationship between the information, evaluation processes and regulation applied to each substance is considered. At the level of screening or inclusion in the CoRAP, the possibility to apply category or read-across is not verified, while it may need to be justified if used as a basis to request information under SEv.

ECHA and MSCAs are already gaining experience on this new approach and addressing questions on efficiency and transparency. There is an obvious need to invest more resources in the screening phase. The further development of the grouping approach for substances should aim at optimising the whole process from screening to regulatory actions, with the view that the early investment of resources in the screening phase will pay off during the subsequent phases. This would enhance the economy of both Member States' and ECHA's resources across different process phases of the regulatory strategy, e.g. manual screening, collaborative approach, CCh, SEv, and regulatory risk management actions.

There was general support for the overall strategy. It was recognised that before including a group in the CoRAP, a good level of pre-assessment is required. It should be clear which substances should be included in the CoRAP, i.e. the boundaries of the group, as well as the opportunities that this selected grouping approach provides. Without pre-assessment, the 12-month evaluation period may be too short for the evaluation of a complex group.

The evaluating MSCAs were encouraged to interact with the Registrant(s) already before including the substances in the CoRAP, so that industry could support the proposed group and provide upfront as much information as possible.

Some practical means for addressing substances by group were discussed, such as:

- for including groups in the CoRAP, all group members should preferably be listed as separate entries, with the group clearly indicated by a footnote and/or other editorial means;
- the relations of the substances in the group should be explained also in the justification document;
- a pilot project to simplify the decision drafting for requests concerning a group of substances – the goal of the pilot project to be started is to address group-related concerns with one common decision instead of issuing separate decisions for each substance in the group.

4.2.3. Optimisation of compliance check and substance evaluation interplay

In the SEv workshop in 2015 the conclusion was that “CCh needs to support SEv by filling standard data gaps”. Thus, CCh is normally performed for all CoRAP substances before starting SEv. Whenever possible (and when considered useful to accelerate the process), SEv has been started in parallel to CCh, rather than awaiting the CCh conclusion.

In general, there was a plea for more flexibility and support to explore possibilities for further integration of the two evaluation processes (SEv and CCh). There are two objectives:

1) to reduce the time spent on obtaining relevant missing information on the substance;
2) the more efficient use of ECHA’s and MSCAs’ resources.

The analysis presented at the workshop outlined that the main factor determining the overall time needed to reach a conclusion on a concern is the need for subsequent decision-making rounds to generate relevant information. In this respect, if standard information is required via CCh before deciding on further requests under SEv, a further integration of the CCh/SEv processes may not be able to prevent the need for subsequent decisions. In such a case, the integration may have only limited impact in shortening the overall process time. However, a more flexible interplay can allow for a better use of MSCAs’ resources in support of ECHA to address information needs.

The following different models for a better interplay were discussed:

- Fine-tuned current approach: When parallel SEv/CCh is feasible, it should start immediately when the substance is included in the CoRAP.
- Integrated model: Integration of SEv/CCh processes regardless of whether the missing information seems to be interlinked and conditional to each other requiring sequential testing strategy. The MSCA would start the evaluation and identify both CCh and SEv types of request, handing over the CCh type of requests to ECHA for further processing. Very close cooperation between the evaluating MSCA and ECHA is required as the SEv and CCh draft decisions would need to be processed together;
- Incorporation model (proposed by Germany): evaluating MSCA would address also any standard information requests under SEv, i.e. there would be no separate CCh process at all.

None of the models was considered superior to the others, and it was clear that each model had some associated risks and/or challenges. It was considered premature to simply select a model and start implementing it, since one model may not fit to all cases and there was not enough knowledge about how these different models would work in practice. There was support **to start a pilot case** to explore new ways of integrating CCh and SEv and the related practicalities and use of resources. However, first there is a need for detailed legal analysis of what is feasible.

4.3. Substance evaluation follow-up

4.3.1. The follow-up evaluation under SEv

Regarding the timelines for the follow-up of evaluation, ECHA’s interpretation of Article 46(3) and (4) of the REACH Regulation is that within 12 months of receiving all information requested in a decision, the evaluating MSCA:

- examines the new information; and
- within the same 12 months, concludes the evaluation; or
- if necessary, drafts a second/further decision.

It was noted that it is important for the evaluating MSCA to inform ECHA when it considers the actual follow-up time to have started, i.e. provides the date for when all the requested information has been (or has not been) submitted by the Registrants.

A SEv decision specifies a deadline (or deadlines) by when the requested information must be submitted by the Registrants. The expectation is that the Registrants comply with this deadline and duly submit the dossier updates with all requested information. However, experience shows that sometimes there are delays with the submissions for several different reasons. The policy on how to deal with delayed dossier updates was discussed with respect to the level of tolerance before reporting to the enforcement authorities. Some participants called for a stringent approach, while others flagged the importance of understanding the nature of the practical difficulties that the Registrants may have encountered while generating the data, which may have resulted in the late provision of the requested information.

A parallel was drawn to dossier evaluation follow-up practice, where ECHA may, for a limited time period, refrain from issuing a statement of non-compliance (SONC) based on the Registrant's justified reasons (e.g. technical difficulties with the testing, but test ongoing) for a delay in submitting the requested information. At the same time, it was noted that SEv is a concern-based process and hence a more stringent approach could be applied on SEv decisions. What remains important is that MSCAs are aligned in their approach. As the topic is closely related to the enforcement authorities' activities and their priorities, it would also need to be discussed in the Enforcement Forum as well as in the Competent Authorities for REACH and CLP (CARACAL) meeting.

The following tools were presented to support efficient communication between the evaluating MSCA and ECHA:

- a monthly report of dossier updates in S-CIRCABC to support the evaluating MSCA's efforts to spot decision-relevant dossier updates;
- a SEv-specific follow-up web form for the indication of the start/not start/delay of the 12-month evaluation period of the evaluating MSCA as well as of enforcement activities.

In this context, it was reiterated that the Registrants are advised also to inform ECHA/the evaluating MSCA using a specific web form that the submission of the requested information has been made.

Furthermore, it was discussed to strive for the following timelines during the communication process between the evaluating MSCA and ECHA:

- Evaluating MSCA to submit the web-form notification on the status of the 12-month evaluation period within 1 month after submission of the requested information by the Registrant.
- In the case of no or insufficient submission of the requested information, the evaluating MSCA should submit a SONC intention within 1 month from the relevant insufficient dossier submission or passed deadline of the decision.
- Subsequently the SONC documentation should be sent by the evaluating MSCA to ECHA at the latest 3 months after the insufficient dossier submission.

ECHA will update the instructions for the SEv follow-up process and envisage the development of SEv-specific SONC and SEv enforcement type decision templates.

4.3.2. From substance evaluation to regulatory risk management

Several general recommendations were reiterated by the ECHA Secretariat:

- the intended follow-up regulatory actions after SEv should be thought and planned ahead;
- proportionality of the proposed measures should be considered – weighing regulatory impact against the effort required of all actors to get the measures in place;
- once SEv is concluded, the relevant regulatory risk management actions should be promptly initiated;
- parallel processes may also be possible if they are suitable for speeding up the overall conclusion on regulatory risk management;
- in the case that the evaluating MSCA has no resources for the follow-up actions, it should inform other MSCAs and ECHA for consideration on who could take over the actions.

Member State representatives raised a concern regarding apparent difficulties with the relation of the mandates of the Member State Committee and the Committee for Risk Assessment. The Member State Committee is at first asked to conclude on the generation of information, and this is followed by the Committee for Risk Assessment deciding on whether the information is sufficient for classification and labelling based on CLP criteria.

It was acknowledged that further integration of REACH and CLP processes from early screening until adequate regulatory risk management would help to ensure that fit for purpose data is generated. This would require enhanced cooperation of evaluation and regulatory risk management teams in Member States and ECHA. This should be pursued already at the early stage of the evaluation, and should ensure the smooth processing of most cases through the Committees. There may still be a few challenging cases for which more discussion is needed between the Member State Committee and the Committee for Risk Assessment on how to best handle them.

4.4. Legal issues and appeals on substance evaluation decisions

Based on the workshop's closed session discussion, a number of conclusions can be drawn on legal issues and appeals on substance evaluation decisions.

Overall, it was noted that between 2008 and 2017 (until 26 September 2017), ECHA's Board of Appeal (BoA) received 19 appeals concerning ECHA's substance evaluation decisions, which represents 18 % of all appeals. One BoA decision has been taken to the EU Court and the case is still pending.

The informal learnings presented by ECHA's Legal Affairs unit on relevant SEv and DEv decisions of the BoA were appreciated. While the decisions of the BoA are case-specific, some more general learnings can be inferred, even if care must be taken not to over-interpret the decisions.

Open discussion with the BoA was welcomed. The BoA explained that it was happy and willing to contribute to events such as this workshop and to discuss relevant issues with Member States. The two BoA members present stressed that the BoA decisions are case-specific and it is to be expected that different people sometimes have different interpretations of them. They also emphasised that the BoA is an independent ECHA body and that its decisions may be appealed to the EU Courts. The BoA members emphasised that it is crucial to address all relevant elements in SEv decisions, including the proportionality of the requested information and how Article 25 and relevant comments by the Registrant have been addressed.

Interventions by the evaluating MSCA in SEv appeal cases in support of ECHA's defence were found useful for both ECHA and the evaluating MSCA. Collaboration between ECHA and the evaluating MSCA has been working well and it is important that the view of the evaluating MSCA is heard by the BoA. Good preparation is also key when it comes to carrying out interventions, including oral hearings before the BoA.

5. Key messages

Overall, there was a consensus on the strategic importance of the integration of different REACH and CLP processes and prioritisation of the work done. There was also a shared understanding on the importance of seeking measures to speed up the process ("faster and better").

There was a general acknowledgement of success in the substance evaluation process, i.e.:

- there is good progress and contribution by all actors – ECHA (including the BoA), evaluating MSCAs, and the Registrants;
- the quality of SEv evaluations and outcome documents has improved;
- there has been a reduction in the backlog in the decision-making phase.

The following core challenges and opportunities for the future were discussed:

- the addressing of substances by group;
- the collaborative approach between Member States and the industry (COLLA);
- the conclusion that overall impact to the safe use of chemicals is to be considered more important than the lower-than-forecast number of substances under SEv/CoRAP ;
- the need to develop a SEv strategy for low tonnage substances and to consider whether there is a need to change the SEv prioritisation criteria accordingly.

Timelines in relation to SEv were also clarified:

- A SEv decision specifies a deadline (or deadlines) by when the requested information must be submitted by the Registrants. The expectation is that the Registrants comply with this deadline and duly submit the dossier updates with all requested information.
- Regarding the timelines for the follow-up evaluation, ECHA's reading of REACH Article 46(3) and (4) is that within 12 months of receiving all the information requested in a decision, the evaluating MSCA examines the new information and must, within the same 12 months, conclude the evaluation or, if necessary, draft a second/further decision.

Regarding how to speed up and make the process lighter, two specific measures were proposed:

- Sequential testing: Exploring how to avoid multiple decision making rounds.
- Faster throughput in Member State Committee decision making: Exploring the possibility to give a broader mandate to the evaluating MSCA to finalise the drafting of the decision with ECHA support.

6. List of abbreviations

BoA	ECHA Board of Appeal
CLP	Classification, Labelling and Packaging Regulation (EC) No 1272/2008
COLLA	Collaborative approach between Member States and industry
CoRAP	Community Rolling Action Plan
ECHA	European Chemicals Agency
MSCA	Member State competent authority
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SEv	Substance evaluation

Appendix 1. Agenda

Workshop on Substance Evaluation

12 October – 13 October 2017

ECHA Guido Sacconi conference room

Annankatu 18, Helsinki, Finland

Thursday 12 October 2017 **Theme: Substance evaluation – Why, how and without undue delay** **Chair: Leena Ylä-Mononen** **ECHA**	
08:30	Registration
09:00-09:10	Welcome and objectives of the workshop — Chair
	Session 1 Substance evaluation in 2017 - Review of the progress made and how to further speed up getting the results
09:10	ECHA view and expectations • Progress towards the regulatory goals • Review of implemented measures to enhance cooperation • Outlook to 2018-2021 — Claudio CARLON, Lee WALKER, ECHA
	Commission view and expectations — Andrej KOBE, DG ENV
	Member State view and expectations — Lea Stine TOBIASSEN, Danish Environmental Protection Agency
10:00-11:00	Discussion
11:00-11:30	Coffee break - (Demo on ACT, K325)
	Session 2 Effective interplay of evaluation processes and grouping approach
11:30-11:45	Clear substance identity for substances under evaluation, what is needed — Jos MOSSINK, ECHA
11:45-12:15	Discussion
12:15-12:30	Addressing substances by groups under substance evaluation — Norbert BORNATOWICZ, ECHA
12:30 - 13:00	Discussion
13:00-14:00	Lunch break

14:00-14:15	Compliance check and substance evaluation – interplay optimisation	Pia KORJUS ECHA
14:15-14:45	Discussion	
	Session 3 Substance evaluation follow-up	
14:45–15:00	How to get SEv follow-up running efficiently and effectively	Paul KREUZER ECHA
15:00-16:00	Discussion	
16:00–16:30	Coffee break - (Demo on ACT, K325)	
16:30-16:45	From substance evaluation to regulatory risk management - goals of the Regulatory Strategy	Chrystele TISSIER ECHA
16:45-17:00	Preparing the necessary regulatory risk management actions. A Member State perspective	Christian UNKELBACH BAuA, Germany
17:00-17:30	Discussion	
	Session 4 Conclusions of the first day	
	Wrap-up slides and short discussion	
18:00	End of Day 1	

Friday 13 October 2017
Closed session 8:30-16:00

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