ECHA
EUROPEAN CHEMICALS AGENCY

Workshop on Substance Evaluation

Proceedings

Helsinki, 26-28 May 2014

Workshop on Substance Evaluation
Proceedings
Helsinki, 26-28 May 2014

Reference: ECHA-14-R-19-EN
Cat. Number: ED-04-14-651-EN-N
ISBN: 978-92-9244-722-9
DOI: 10.2823/47119
Date: July 2014
Language: English

If you have questions or comments in relation to this document please send them (quoting the reference and issue date) using the information request form. The form can be accessed via the 'Contact ECHA' page at: http://echa.europa.eu/contact

European Chemicals Agency
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of Contents

1. Summary

At the workshop, experiences made so far in substance evaluation (SEv) were discussed. The Member States and industry representatives emphasised the importance of good interaction between industry and the evaluating Member State competent authority (eMSCA) during SEv.

Performance of a compliance check (CCh) by ECHA on CoRAP substances before starting the SEv was highly appreciated to give information on data gaps outside the area of initial concerns related to the substance. It was agreed that MSCAs would notify new substances mainly for the third year of CoRAP updates except when there are justified reasons for earlier inclusion in the CoRAP. Although a CCh is normally performed to fulfil relevant data gaps for standard information requirements before SEv, it is still possible that some data gaps need to be handled under SEv. In this respect, the workshop agreed that a data gap for standard information requirements should be considered as a concern that can be addressed under SEv, in particular when it is linked to the initial concern or relevant for the (regulatory) risk management.

The possibility to target SEv was discussed. SEv is targeted at identified concerns, but the question is whether a screening should be performed to identify any other concerns besides the initial concern(s) indicated in the CoRAP, and whether these additional concerns should always be addressed. It was agreed that as a general principle, consecutive SEvs on the same substance should be avoided to the extent possible. Therefore, a general screening for additional concerns by the eMSCA is recommended. Additional concerns should also always be addressed under SEv, even if they are not related to the initial concern, but case specific considerations in relation to the envisaged or existing (R)RM are also possible.

The handling and publication of outcome documents of the SEv process were extensively discussed. Regarding SEv decisions, the question was posed on how to make them clearer and possibly less lengthy. A common understanding on what to include in the statement of reasons of the (draft) decisions and what to omit was reached. A working group will be established to work on “standardised” approaches for certain information requests and to reflect the decision-making process in the decision. With regards to the SEv report, it was agreed that the Member State’s SEv report is a very valuable “living” internal working document for authorities. The publication of the full SEv report at the end of the evaluation has proven to be rather demanding and therefore a new concept for publication of the evaluation outcomes shall be discussed at the next competent authority meeting (CARACAL) in July.

This workshop provided the opportunity to discuss for the first time the so-called “follow up evaluation” i.e. evaluation of new information that have been provided by the registrant(s) after a decision to request such information. There was agreement that the 12-month period for Member State evaluation should start only when all data requests in a decision are submitted by the registrant(s) and that the registrant(s) are obliged to inform when all information is available to the evaluating Member State. The concept to facilitate enforcement actions when there is non-compliance with SEv decisions was welcomed and will be further developed and discussed within the ECHA Forum too.

2. Introduction

From 26 to 28 May 2014, the European Chemicals Agency (ECHA) hosted a workshop on substance evaluation (SEv). The main scope of the workshop was to discuss and agree on various aspects of the SEv process:

- compliance and concern – issues to be addressed under SEv;
- how to improve and handle outcome documents;
- follow-up evaluation after obtaining new information.

68 external participants from 26 EU/EEA Member States, the European Commission and six from the 18 invited Member State Committee accredited stakeholder observers attended the workshop.

ECHA's Deputy Executive Director, Jukka Malm, welcomed participants and thanked the MSCAs for their commitment in the SEv process. He noted with appreciation that the annual update of the CoRAP is now fully rolling and that 24 substances have already been passed through the decision-making process. He recommended that the work should be fit for purpose and optimised to bring the desired results with the least possible use of resources.

ECHA's Director of Evaluation, Leena Ylä-Mononen was chairing the discussions. This report will only state the key conclusions reached in the workshop and will not record any individual contributions.

Overall, subject to the endorsement of the competent authorities in the CARACAL meeting on 8-10 July, the key conclusions and recommendations will be implemented in the MSCA instructions already available in CIRCABC.

The workshop agenda is included in Annex I.

3. Experiences made and lessons learnt

3.1 INTERACTION BETWEEN EMSCAS AND REGISTRANTS

The experiences of the eMSCAs were gathered through a questionnaire before the workshop and presentations on the experiences were given by MSs and industry representatives.

Communication with and interaction between eMSCAs and registrants is already widely established and generally works well. It was recommended that the interaction should be practised also after sending the final decision and during follow up, notwithstanding that timelines and content of the unanimously agreed decision shall be respected. Furthermore, it was noted that interaction during the three-month appeal period would require special attention.

3.2 EFFICIENCY AND EFFECTIVENESS

The consistency screening of preliminary draft decisions (DDs) performed by ECHA is appreciated by the eMSCAs as a very useful service. In addition, the eMSCAs are encouraged to seek ECHA's advice during the evaluation as early as a question is identified, to increase harmonisation and to avoid accumulating all issues within the short period of time towards the end of the 12-month period.

Although issuing of DDs is one of the generally expected outcomes of an SEv, some participants indicated that the proportion of evaluations leading to DDs as an indicator of the SEv outcome should not be taken as the only nor the best measure for effectiveness of the process. The use of such an indicator in isolation can motivate the eMSCAs to make requests for information even when not strictly necessary to clarify major concerns. Therefore, a related aspect to be assessed is the relevance of the requests for (regulatory) risk management. Furthermore, other ways for MSCAs to gather or generate information such as through informal interaction with the registrants or by grouping approaches, should also be valued. Other aspects of efficiency are associated with the SEv outcome documents, where the most efficient way of working, still ensuring transparency, shall be sought (see "outcome documents in SEv").

For effectiveness, a useful indicator appears to be the proportion of evaluations that led to significant changes in (regulatory) risk management. So far only a few final SEv conclusions are available and therefore it might be too early for reasoning or drawing firm conclusions at this point. ECHA plans a review of the efficiency and effectiveness of the SEv process in 2015.

4. Compliance and concern

4.1 SCOPE AND TIMING OF CCH FOR CORAP SUBSTANCES

The MSCAs appreciate that the overall CCh is performed by ECHA before SEv, mainly so that information on data gaps outside the area of the initial concerns can be received. Participants agreed to notify new substances mainly for the third year of the CoRAP update, except where there are justified reasons for earlier inclusion in the CoRAP. The inclusion of substances in the third and last year will allow ECHA to perform this overall CCh with an assessment of SID and hazard information. ECHA confirmed that CChs for CoRAP substances are prioritised under dossier evaluation processes. Participants indicated they need more time for reply to ECHA's outcome of the CCh and proposed four to six weeks instead of two weeks. ECHA felt that extending the timeline to six weeks would be possible, but that the shorter response time should be of mutual interest to maintain an effective process.

For newly notified substances included in the second year of the CoRAP, ECHA performs only SID-targeted CChs on dossiers from lead registrant(s), individual submissions and opt-outs and occasionally also of dossiers of some members.

It was stressed that the responsibility on unambiguous SID lies on industry and that the SIEFs have to ensure substance sameness within their joint submissions.

4.2 SCOPE OF SEV

Although a CCh is normally performed to fulfil relevant data gaps for standard information requirements before SEv, it is still possible that some data gaps need to be handled under SEv. Agreement was reached that a data gap is to be considered as a concern. If linked to an SEv initial concern, it has to be addressed within SEv. Identified data gaps not linked to the initial concern, should also be addressed under SEv, if relevant for the (regulatory) risk management (R)RM. Furthermore, an alignment to dossier evaluation policy, e.g. on topics such as read-across and weight of evidence, is however needed.

It was also agreed that additional requests may be triggered by proposals for amendments (PfAs) by other MSs or ECHA, thus providing a safety net to avoid missing possible concerns.

4.3 TARGETING IN SEV

It was agreed that as a general principle, consecutive SEvs on the same substance should be avoided as much as possible. General screening for additional concerns by the eMSCA is recommended. The eMSCA needs to document what has and what has not been evaluated or screened and to justify its approach. For clarification, ECHA is to give further description/definitions of "screening" and "evaluating".

When the eMSCA identifies an additional concern, those concerns closely related to the initially identified concerns should always be addressed under SEv. Whereas, for additional concerns that are not related to the initial concern, ECHA proposes a flexible approach: these concerns should also be addressed, unless they appear not to be relevant in view of the envisaged or existing (R)RM. It is also acknowledged that very difficult cases (e.g. nanoparticles) may need a targeted evaluation for various reasons.

Other MSs and ECHA may propose, if necessary, in the PfA phase new concerns to be addressed. However, addressing new concerns at this late stage of the process may be difficult for the eMSCA and the registrants.

4.4 COST SHARING AMONG THE CONCERNED REGISTRANTS

The issue of cost sharing among registrants was raised during the discussion on requesting information. It was clarified that all registrants of a substance (with standard registrations) at the time of the draft decision are addressees of the SEv decision, irrespective of tonnage. With regard to cost sharing, other factors besides tonnage may play a role, e.g. specific impurities, uses or exposure.

ECHA cannot address these issues in the decision and therefore cost sharing is up to the SIEF. It was however acknowledged that there is no guidance for registrants, in particular for information requests that are beyond standard registration requirements. It was noted that Article 27 does not address cost sharing other than that which is registration related and therefore there is no dispute settlement mechanism in place either.

5. Outcome documents in SEv

5.1 CONCLUSION DOCUMENT

Issuing a conclusion document is a legal requirement under Article 48. The eMSCA has the ownership of the conclusion document. The legal text does not foresee consultation or the consent of other MSs. However, some informal interaction would be advisable on a case-by-case basis:

It was agreed that if other MSCAs than the eMSCA have a specific interest or relevant information on the substance, they should contact the eMSCA as early as possible. Furthermore, the eMSCA may, on its own initiative, wish to ask for feedback from other eMSCAs during the 12-month evaluation period. The eMSCAs are encouraged to use the CIRCABC platform as a facilitator for such information exchange.

The SEv conclusion document should be prepared by the eMSCA within four months of the conclusion of the SEv. Concerning the relation of the conclusion document with the (possible) RMO analysis document, it was agreed to have two options available for eMSCAs:

- If RMOA can be made within four months or within a reasonable time or if RMOA is not required, a specific conclusion (i.e. indicating which specific regulatory follow up is needed) can be prepared. In this case, the SEv conclusion could also include the outcome of the RMO analysis, therefore a separated RMOA document would not be required.
- If RMOA is not possible within four months or within a reasonable time, but is required to decide on which specific regulatory follow up, a conclusion document can be prepared with a general conclusion only, and an indication that the outcome of an RMO analysis will be published later.

Some MS participants also raised the concern that even though they do the SEv, they might not be able to perform the RMOA or follow-up regulatory actions. Hence, they would prepare only the conclusion document for SEv.

5.2 DECISIONS

The addressee for an SEv decision is the registrant. Therefore the document has to give clarity and rationale for the addressee and to be a clear and standalone document. Whereas ECHA expressed concern on the excessive length of the decision, the workshop participants were of the view that the length of the document is only of secondary concern.

Some recommendations on how to draft decisions have been discussed in the workshop and will be specified in ECHA's instruction documents. Only key issues from the registrant ´s comments or the MSCA's and ECHA's PfAs need to be reflected in the decision. Improvement in the decision can be achieved by dropping certain procedural elements, e.g. amendments in line with the registrant's comments, or not accepted PfAs. These issues can instead be addressed in the MSC minutes where relevant. The procedural steps themselves are documented in section I of the decision ("Procedure") and this can be kept rather short.

ECHA proposed and participants agreed to have a dedicated person that takes care of the drafting of the decision and who attends the MSC meetings to be available for the final drafting.

The workshop agreed to establish a Working Group on best practice for SEv decisions and some MSs already volunteered. Confirmation of the establishment of the group will be searched in writing in the next CARACAL.

ECHA will draft a mandate for the Working Group, i.e. to:

- Address the identified main difficulties in drafting SEv decisions;
- Support the revision of DD instructions for simplification;
- Identify best practice:
- Support the development of illustrative examples.

5.3 SEV REPORT

This was the topic most extensively discussed. The following conclusions supported by the majority of the MS participants, with diverging views expressed by some MS representatives and in particular industry observers.

According to the majority, the main purpose of the SEv report, as it currently stands, is to be a "living" internal working document for authorities and eMSCAs will continue to record the assessment in such a document. It was agreed by the majority not to share the whole SEv report with registrants. However, the eMSCA may share parts or elements of it with registrants during or after the 12-month period to clarify the need for possible data requests.

Preparing the SEv report, as it currently stands, for publication purposes is a significant resource drain for eMSCAs and ECHA, not least due to confidential business information. Therefore, it was proposed that the final SEv report in its current form would no longer be published. At the same time, it was acknowledged that transparency of the SEv outcomes should be ensured. Possible alternatives were discussed, including publishing a summary of the current SEv report as a standalone summary document or to include a summary of the assessment in the conclusion document, which in any case shall be made publicly available. The following process to conclude on the issue was agreed:

- Based on ECHA's proposal, CARACAL will endorse, at the principal level, the new concept for publication of the evaluation and its findings;
- WG on SEv report continues to define essential/minimum elements of the current SEv report to be published;
- Upon agreement, ECHA revises templates, seeks written comments and aims to finalise the new template by the end of 2014 so that it is available for evaluations concluded in 2015.

6. Follow-up evaluation

This workshop provided the opportunity to discuss for the first time the so-called "follow-up evaluation" i.e. evaluation of new information that have been provided by the registrant(s) after a decision to request such information.

There was agreement that the legally provided 12-month period (Article 46(3)) for the Member State's evaluation should start only when all data requests in a decision are submitted by the registrant(s). The registrant(s) shall be requested (in the decision and/or notification letter to the decision) to inform the eMSCA/ECHA of the relevant update when all data are submitted. As a benefit, neither the eMSCA nor ECHA will need to repeatedly search REACH-IT to find any relevant update. The registrants will also have clarity on the subsequent timeline for the follow-up evaluation.

The follow-up of multiple decisions on a same substance addressed to different registrants with possibly different deadlines needs to be considered further and ECHA will provide legal analysis to enable a workable and meaningful solution.

If the requested information is not submitted by the deadline set in the decision, the same process implemented under dossier evaluation can be adapted under substance evaluation. Under dossier evaluation, ECHA sends a "statement of non-compliance" (SONC) letter with the decision to the relevant Member State authorities, in copy to the Forum for enforcement focal point and the registrant. The similar concept of a SEv-SONC to aid enforcement actions in the case of non-compliances was welcomed and will be further developed. The main complication stemmed from the fact that under SEv, there are multiple registrants concerned by the same request and possibly multiple enforcement authorities that would need to act. There was agreement that the eMSCA would propose to ECHA the sending of an SEv-SONC letter, and to prepare the attachment to the letter which specifies what information is still missing. ECHA's Forum for Exchange of Information on Enforcement will continue discussions on how to conduct enforcement in the case of SEv decisions that are not complied with by registrants.

A revised document on the follow-up evaluation is aimed to be submitted for written comments.

7. List of abbreviations

CA	Competent authority
CARACAL	(Meeting of) Competent authorities for REACH and CLP
CCH	Compliance check
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CoRAP	Community rolling action plan
DD	Draft decision
ECHA	European Chemicals Agency
eMSCA	Evaluating Member State competent authority
LR	Lead registrant
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
PfA	Proposal for amendment
RCOM	Response to comment
RMO	Risk Management Option
RMOA	Risk Management Option Analysis
RRM	Regulatory Risk Measurement
SEv	Substance Evaluation
SIEF	Substance information exchange forum
SID	Substance identification
SONC	Statement of non-compliance
WG	Working group

Annex I – Agenda

Workshop on Substance Evaluation
26-28 May2014
ECHA Conference Centre, Annankatu 18, Helsinki, Finland
Chair : Leena Ylä-MononenDirector of Evaluation

Monday 26 May 2014 **Afternoon session**		
12.00	Registration	
13.00	1. Welcome	Jukka Malm Deputy Executive Director ECHA
13.15	2. Introduction – Aim of the workshop	Leena Ylä-Mononen Director of Evaluation ECHA
Session 1 Lessons learned and potential for efficiency gains from previous rounds of Substance Evaluation		
13.30	3. Member state perspective	Johanna Barthelemy-Berneron, Corinne Belveze France
13.45	4. Registrant's perspective	Erwin Annys, CEFIC (presenting), Hugo Waterschoot, EUROMETAUX
14.00	5. Coordinator's perspective	Claudio Carlon Head of Unit Evaluation II ECHA
14.15	Discussion	All
14.50	Coffee break	
Session 2 Compliance and Concern – The issues to be addressed under Substance Evaluation		
15.20	6. Compliance and concern: What to address under SEv?	Giovanni Bernasconi Evaluation, ECHA
15.40	7. How to ensure clear substance identity for substances under SEv?	Silvia Demattio Registration, ECHA
16.00	8. Targeting under Substance Evaluation	Evelin Fabjan Evaluation, ECHA
16.20	Discussion	All
18.00	Get together reception at ECHA (1 hour)	

Tuesday 27 May 2014 Morning session		
Session 3 Substance Evaluation outcome documents– Purpose, content and structure		
09.00	9. State of the play with outcome documents	Paul Kreuzer Evaluation, ECHA
09.20	10. Report from Member State Working Group on SEv Report	Mark Schwägler Federal Institute for Occupational Safety and Health (BAuA), Germany
09.40	Discussion	All
10.10	Coffee break	
10.40	11. How to facilitate short(er) and clear decisions?	Jane Caley Evaluation, ECHA
11.00	Discussion	All
12.15	Lunch	

Tuesday 27 May 2014 Afternoon session		
Session 3 continued Substance Evaluation outcome documents – Purpose, content and structure		
13.15	12. Introduction to the World Café session	Leah Wollenberger Evaluation, ECHA
13.30	13. World Café discussions (1) Purpose and content of SEv report (2) Shall (interim) SEv report be shared with the Registrants and what to publish in the end? (3) Conclusion document; consultation with other MSCAs (4) Short and clear SEv decisions (Coffee will be served during session)	All
15.20	Break	
15.40	Reporting back from World Café	Hosts from World Café
16.40	Plenary discussion	All
18.00	End of Day 2	

Wednesday 28 May 2014 Morning session		
Session 4 Follow up evaluation after obtaining new information		
09.00	14. Challenges in implementing new ideas for outcome documents – Discussion	All
09.30	Setting up the Follow up process	Pia Korjus Team Leader Substance Evaluation, ECHA
10.00	Role of Forum under Substance Evaluation	Maciej Baranski Team Leader Forum Secretariat, ECHA
10.20	Discussion	All
11.00	Coffee break	
Session 5 Wrapping up/Conclusions		
11.30	Reporting back from special closed session "meeting of authorities' legal experts"	Timo Rocke Regulatory Affairs, ECHA
11.50	Discussion/further recommendations and conclusions	Leena Ylä-Mononen Director of Evaluation ECHA
12.45	Closing of the Workshop	Leena Ylä-Mononen Director of Evaluation ECHA
13.00	End of the Workshop	

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

ECHA-14-R-19-EN - ED-04-14-651-EN-N - ISBN: 978-92-9244-722-9 - DOI: 10.2823/47119

Publications Office