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Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations

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Recommendations on best practices for the informal interaction between evaluating MSCAs and registrants during substance evaluation

Background

The Workshop on Substance Evaluation (SEv) at ECHA on 23-24 May 2013 agreed to set up a working group to propose recommedations for harmonising the interactions between the evaluating Member States (eMSCA) and the registrants during substance evaluation. The group was led by Ireland and a Cefic representative and members from the Netherlands, Germany, the United Kingdom, France, Denmark, the Commission and ECHA. The Competent Authorities for REACH and CLP (CARACAL) endorsed these recommendations in a meeting in Brussels on 27 – 28 November 2013 and ECHA agreed to publish those on its website.

This document is addressed to the eMSCAs and the registrants of substances in the Community rolling action plan (CoRAP). The aim of the recommendations is to give guidance for a common approach and create a level playing field for interactions among the evaluating Member States and the registrants. These recommendations complement the leaflet "Substance evaluation under REACH – Tips for registrants and downstream users".[1]

The rolling nature of the CoRAP means that substances are listed for evaluation over a three year period: the current evaluation year (Year N) and subsequent years (Years N+1 and N+2). The working group mainly focused on the informal interaction between the eMSCA and registrants for substances under evaluation in Year N. The proposals presented in this paper are recommendations for best practice to aid open and efficient interaction between the eMSCAs and registrants and are based on the experience gained from the first year of evaluations. They are not legally binding and not meant to be exhaustive. The working group concluded that ultimately the need and scope of any interaction will be specific to each evaluation and for the eMSCA to decide. The recommendations will be revised when necessary based on further experiences of eMSCAs and registrants in the SEv process. Further to the recommedations for the interactions, the group pointed out that ECHA should collate and update SEv procedural information on the ECHA website to assist registrants.

The main conclusions and recommendations about taking the interactions are presented below. Further detail is presented in appendix 1 to this document.

Summary of the main conclusions and recommendations of the working group

Substances on the CoRAP in Years N+1 and N+2:

- For substances listed on the CoRAP in Years N+1 and N+2, it is proposed that interactions are focussed to eMSCAs providing clarifications regarding the SEv process and the registrant providing information on the status of any on-going testing or planned dossier updates which might affect the SEv.

[1] ECHA-12-L-10_EN published on ECHA website

For substances listed on the CoRAP in Year N:

- If contact has not already occurred, it is recommended that the eMSCAs make contact with registrant(s) shortly after publication of the CoRAP.

- To facilitate efficient communication, registrants are encouraged to appoint a single representative or "Registrants Contact Point" for discussions with eMSCA. (It is proposed that a template letter is developed which could be signed by Registrants Contact Points confirming their appointment.)

- It is recommended that all registrants are copied on the first correspondence from the eMSCA to ensure they are aware of the evaluation. The working group consider that it would be beneficial if a mechanism to inform all registrants could be developed. In the absence of such a mechanism and where there are a large number of registrants, eMSCAs should contact the lead registrant in the first instance.

- Since the scope and complexity of evaluations will differ between substances, it was considered that no fixed timings for subsequent contacts between the eMSCAs and registrants can be proposed.

- Registrants are encouraged to discuss and agree with the eMSCA in advance the scope and timing of any dossier updates.

- It was considered that further discussion regarding the function of the SEv report and the type and extent of the content is required before a recommendation can be made as to whether the draft SEv report, or elements of it, can be shared with registrants. It is proposed that this should be a core topic for agreement at a later ECHA SEv workshop(s) or expert meeting(s). In the interim it is proposed that the decision to share the SEv report, or aspects of it, with registrants can be decided on a case by case basis by the eMSCA.

- The draft decision should not be shared with registrants outside of the formal commenting period.

- It is suggested that the eMSCA informs the Registrants Contact Point e.g. via email, when the evaluation is completed.

- During the formal 30-day commenting period on the draft decision, it is recommended that registrants inform eMSCAs of the scope of any planned dossier updates in support of their comments and agree in advance the timeframe for submitting such updates, which should be submitted within 60 days after notification of the draft decision to the registrants.

- Preferentially one representative, the Registrants Contact Point, should send consolidated comments on the draft decisions and proposals for amendments on behalf of all registrants.

Appendix 1: Conclusions and recommendations of the working group

The main source of information for the evaluation is the registration dossiers. All relevant information should be included in the registration dossiers and registrants are required to always keep their registration dossiers up to date. The working group noted that the inclusion of a substance on the CoRAP should not specifically trigger any new data generation or dossier updates by the registrants. However, registrants are encouraged to inform the eMSCA as early as possible of the scope and timing of any planned dossier updates.

A. Substances listed on the CoRAP in Year N+1 and N+2

For substances listed for evaluation in Years N+1 and N+2, it is noted that the eMSCAs have not yet had an opportunity to evaluate the registration data. In addition, the timing of the evaluation, whether the substance stays listed in the CoRAP and the initial concern(s) identified for substances listed in Years N+1 and N+2 may change with subsequent CoRAP updates, e.g. in response to dossier updates. Therefore, it is proposed that interactions for substances in Years N+1 and N+2 be focussed to eMSCAs providing clarifications regarding the SEv process, where requested, and the registrant providing information on the status of any on-going testing, data gathering or planned dossier updates (e.g. new information, change of identified uses, etc.) which might affect the SEv.

The draft CoRAP update published on ECHA website in autumn each year gives registrants an early indication of substances potentially to be evaluated in Years N+1 and N+2. In addition, publication of the CoRAP justification documents at the annual CoRAP update provides registrants with details of the initial concern(s) identified which triggered the inclusion of the substance on the CoRAP.

B. Substances listed on the CoRAP in Year N

For substances listed on the CoRAP in Year N, there are four stages where interaction between the eMSCA and registrant could be anticipated and these are further discussed below.

1. Before evaluation begins

The draft CoRAP update, along with the contact details of the eMSCAs, is published on ECHA website in autumn each year. Therefore, registrants can contact eMSCAs at this stage, for example to inform of any on-going testing or planned dossier updates. The eMSCA may also proactively contact the registrant at this stage.

2. During the 12 month evaluation period

Registrants Contact Point

As the MSCAs are responsible for substance evaluation, it is recommended that the eMSCA makes contact with the registrant(s) shortly after publication of the CoRAP, if they have not already done so. This initial contact is intended to provide the registrants with a point of contact in the eMSCA for further communication, to explain the SEv process (if necessary), and to encourage the registrants to appoint a single representative or “Registrants Contact Point” for further discussions with the eMSCA. The Registrants Contact Point can be, for example, the lead registrant, another registrant or a consultant. The appointment of a Registrants Contact Point should facilitate efficient communication between the eMSCA and registrants during the evaluation period. It is recommended that eMSCAs also inform ECHA of the identity of Registrants Contact Points to assist also ECHA in communicating with the registrants during the evaluation period.

It is proposed that a template letter should be developed which could be signed by the Registrants Contact Point, confirming that he had consulted with other registrants and they are in agreement that he should act as the Registrants Contact Point. A copy of this letter could be given to the eMSCA and the other registrants.

It is proposed that the Registrants Contact Point would be responsible for sharing and collecting relevant information and reporting back to the group of registrants. However, the appointment of a Registrants Contact Point would not exclude the possibility for interaction between the eMSCA and registrants other than the Registrants Contact Point e.g. for technical support, confidential issues, downstream uses etc. In any case, it should be clear that all registrants have the possibility of contacting the eMSCA directly.

While it is recommended that all registrants are copied on the first correspondence from the eMSCA to ensure that they are aware of the evaluation, this may not be feasible where there is a large number of registrants. Therefore, in order to overcome this, the working group consider that it would be beneficial if a mechanism to inform all registrants could be developed, for example sending the initial contact communication prepared by the eMSCA to all registrants of the substance via REACH-IT. However, in the absence of this functionality for eMSCAs in REACH-IT it is suggested that the eMSCA contacts the lead registrant in the first instance. Registrants are also encouraged to consult ECHAs website for updates on the SEv process.

Contact between the eMSCA and Registrants Contact Point can be in the form of meetings (either face to face or teleconference) or written correspondence. If all parties agree, brief informal notes or action points can be prepared following meetings to ensure agreed actions and timings are clear and documented. These could also be used by the Registrants Contact Point to communicate the status with other the registrants. However, it should be noted that interaction remains informal in nature.

Where the eMSCA is contacted by other parties, e.g. industry associations, consortia or consultants, the eMSCA is reminded of potential confidentiality issues and it is suggested that the eMSCA obtain confirmation from the lead registrant or Registrants Contact Point that the third party is acting on behalf of the registrants (i.e. is not part of provisions in Articles 50 – 52 of the REACH Regulation).

Scope of contact

At the time of the initial contact, it is expected that the eMSCA would not yet have had the opportunity to evaluate the registration data in detail and therefore no in depth discussion regarding technical data is foreseen. Since it is expected that each eMSCA may need to provide some background information to registrants on the SEv process during this first contact, the working group recommends that ECHA collates and updates the SEv procedural information on the ECHA website so that eMSCAs have the possibility to direct registrants to a specific section of the website in their initial communication. This would facilitate all registrants obtaining the same standardised level of information at the start of the process. In addition, the working group propose that ECHA investigate the possibility of a recorded webinar or short practical guide for registrants regarding the SEv process.

When the eMSCA has had an opportunity to review the registration data, further communication with the Registrants Contact Point may be required e.g. to request clarifications regarding the registration data or further details regarding unpublished studies reported in the registration dossier. Also, since the evaluation is not limited to the initial concern, other aspects of the registration dossier could be discussed with the Registrants Contact Point. Therefore, subsequent contacts from the eMSCA will depend on the scope and complexity of the evaluation and so no fixed timings for interaction can be recommended since each evaluation will be different. As discussed above, all registrants always have the possibility

to contact the eMSCA during the evaluation period, in particular where they have information which would assist or impact the evaluation.

The start of a substance evaluation should not trigger the requirement for updates of the registration dossiers since all relevant information should already be included in the dossiers. Updates of registration dossiers are difficult to incorporate into the SEv timeline and therefore it may be difficult for the eMSCA to take dossier updates into account. Registrants are encouraged to discuss and agree with the eMSCA in advance the scope and timing of any updates, particularly where they are planned during the evaluation period.

SEv report

The working group noted that further discussion regarding the function of the SEv report and the type and extent of the content is required before a recommendation can be made as to whether the SEv report, or elements of it, can be shared with registrants during the 12 month evaluation period. From a practical perspective, it is noted that the SEv report is a work in progress at this stage of the evaluation and it may be difficult for the eMSCA to ensure CBI[2] and IPR[3] issues are addressed to allow the SEv report to be shared, particularly where there are a large number of registrants. It is noted that sharing the draft SEv report during the 12 month evaluation period may give registrants an indication of what information will be requested in the draft decision ahead of the formal 30-day commenting period for registrants to comment on the draft decision. Thus, in the case where the draft SEv report is shared only by some eMSCAs, this may lead to an unfair advantage for those registrants who receive the draft SEv report knowing issues ahead of the formal commenting period on the draft decision.

Since a common understanding of the function and scope of the SEv report is needed, the working group propose that this should be a core topic for agreement at next workshop or expert meeting. In addition, consideration should also be given to the development of an updated SEV report template which would facilitate easy sharing of SEv report, or elements of it, with registrants. It is proposed that in the interim, the decision to share the SEv report, or aspects of it, with registrants can be decided on a case by case basis by the eMSCA.

SEv draft decision

It is strongly recommended that the draft decision is not shared with registrants during the 12 month evaluation period. REACH provides for a formal and fixed timeframe for registrants, and downstream users if relevant, to comment on the draft decision at the end of the evaluation period. Sharing of the draft decision ahead of this deadline may create legal expectations and unequal treatment of registrants. Also, from a practical perspective, the exact text of the draft decision might only be drafted at the end of the evaluation period which makes sharing the text during the evaluation period difficult. However, it is recognised that in some cases the eMSCA may wish to obtain input from registrants on specific technical aspects during the drafting of the decision.

3. On completion of the evaluation

Registrants Contact Point

By the end of the 12 month evaluation period, the eMSCA must complete their evaluation and submit to ECHA the required SEv outputs, including the SEv report and draft decision (if required). It is suggested that the eMSCA informs the Registrants Contact Point (e.g. via email) when the evaluation is completed. Where the eMSCA has prepared a draft decision, it is

[2] CBI = Confidential Business Information
[3] IPR= Intellectual Property Rights

suggested that the eMSCA also indicates that a draft decision has been prepared and that ECHA will formally invite the registrants via REACH-IT to comment on the draft decision. Such a communication would signal the end of the informal communication during the 12 month evaluation period and the start of the formal commenting procedure as outlined in REACH. It also flags to registrants that they should expect an invitation from ECHA to comment on the draft decision during the 30 day commenting period. Likewise, in the case where the evaluation is completed without a draft decision, it is suggested that the eMSCA indicates this in the communication to inform the registrants not to expect a draft decision.

SEv report and draft decision

As discussed above, no recommendation can currently be made as to whether the SEv report can be shared with registrants. It is noted that at this stage of the process, an interim version of the SEv report is available but the same concerns regarding addressing CBI and IPR issues remain, if relevant. Pending agreement on the function and content of the SEv report, it is suggested that the decision to share the SEv report with registrants is decided on a case by case basis by the eMSCA. As REACH provides for a formal and fixed timeframe for registrants to comment on the draft decision, it is recommended that the eMSCA does not share the draft decision with the registrants before formal submission of the draft decision to the registrants by ECHA.

30-day commenting period for registrants on the draft decision

During the formal 30-day commenting period, it is expected that registrants would submit to ECHA comments on the draft decisions and, if necessary, any information relevant to the draft decision in a dossier update. The registrants are encouraged to speak with one voice and it is recommended that one representative, the Registrants Contact Point, should send consolidated comments on the draft decisions on behalf of all registrants. During this period, registrants also have the opportunity to informally request clarifications from the eMSCA regarding information requests in the draft decision. The working group noted a previous agreement[4] that **eMSCAs would consider dossier updates** received before notification of the draft decision to other MSCAs and ECHA for commenting **if the dosser update is agreed in advance with the eMSCA and is submitted within 60 days after notification of the draft decision to the registrants.** Therefore, registrants are encouraged to inform eMSCAs during the 30 day commenting period of the scope of any planned dossier updates and to agree in advance a timeframe for submitting such updates. However, it is anticipated that no new elements to the evaluation would be introduced following the 30-day commenting period.

Further informal interaction between eMSCAs and registrants outside of the formal 30-day commenting period on the draft decision is expected to be on a case by case basis, and limited to for example, the eMSCAs requesting clarification from registrants regarding their comments on the draft decision following the 30 day commenting period.

30-day commenting period for MSCAs and ECHA on the draft decision

The circulation of the draft decision to other MSCAs and ECHA for commenting signals the end of the informal interaction between eMSCA and registrants. It is noted that no further dossier updates can be taken into account once the draft decision is circulated to other MSCAs and ECHA; the draft decision can only be amended based on proposals for amendment by MSCAs or ECHA. It is recommended that ECHA publish on their website the commenting periods for other MSCAs and ECHA to propose amendments to the SEv draft decisions and the associated Member State Committee meeting dates, so that registrants are aware of the various

[4] Proposal AHCA/09/2013 ad hoc MSCA meeting July 2013, and the subsequent written agreements

commenting periods, although it is noted that general information on the consultation periods would not specify which substances would be addressed in each MSCA consultation round.

In the case where other MSCAs or ECHA submit proposal for amendment on the draft decision, the registrants of that substance are invited by ECHA to formally comment on the proposals for amendments. The commenting period is 30-days. The registrants are encouraged to speak with one voice and it is recommended that one representative, the Registrants Contact Point, should send consolidated comments on the proposals for amendments on behalf of all registrants.

4. After the final decision is issued

The final decision is a stand-alone document which should clearly document the information request. Therefore, discussion between the eMSCA and the registrants on the final decision is not foreseen.

However, the working group noted that for non-standard testing the registrants may wish to obtain further clarifications or advice from the eMSCA regarding for example, the design of the study. However, the registrants should be reminded of the informal nature of such interactions and that the text of the final decision is legally binding.