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Workshop on Substance Evaluation

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Workshop on Substance Evaluation

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1. Executive summary

During the workshop, the first experiences of Member States Competent Authorities (MSCAs) with Substance Evaluation (SEv) were shared among the participants.

A common approach was agreed for the interaction between the Registrants and the evaluating MSCA (eMSCA), although it was recognized that this should be kept flexible. eMSCAs should contact the lead Registrants as early as possible in the process to start the dialogue. Registrants are urged to choose a representative to coordinate and interact with the eMSCA. This representative should preferably be the Lead Registrant.

Registrants were also recommended to inform the eMSCA when they are planning to update their registration dossiers. To enable the interaction and allow the Registrants to update their dossiers early in the SEv process, the MSCA intending to evaluate each substance is published already in the draft Community Action Rolling Plan (CoRAP). In addition, a news alert was published after the workshop on the preferred ways of interaction between registrants and eMSCAs during the substance evaluation process. (http://echa.europa.eu/web/guest/view-article/-/journal_content/cff952ba-b307-46aa-ba73-f88a9d690c9c).

At the workshop, it was concluded that it is in everybody's interest that Registrants coordinate among themselves the interaction with MSCAs/ECHA during the SEv process.

The role of stakeholders other than the Registrants needs further consideration as it was not discussed in detail during the workshop.

The support offered by ECHA to MSCAs throughout the SEv process was welcomed in view of the numerous challenges ahead, such as preparing and sending draft decisions to multiple Registrants while dealing with confidential business information.

Timing and steps of a draft decision in the decision making were extensively discussed at the workshop. Member States have the leading role for deciding to which Member State Committee meeting a draft decision should be scheduled for possible agreement seeking and whether a written procedure on the draft decision is possible.

In relation to the follow up of the SEv process according to Article 48, initial thoughts were exchanged among Member States. Further discussions on this topic were deemed necessary. In particular, it was agreed that the Forum should discuss enforcement issues related to decisions taken under SEv, especially cases where the lead Registrant is not situated in the same country as the eMSCA.

It was recognized that the annual Evaluation Progress Report is an important instrument for communicating the issues to improve dossier quality and in this respect it should include also the results from substance evaluation.

ECHA has prepared allocation criteria for distributing the substances among the Member States. It was agreed that these criteria can be used as a last resort by MSCAs when two or more of them are interested for evaluating the same substance and seek for guiding principles to decide on the final allocation.

With regard to the update of the CoRAP, there was a general consensus that the revision of the selection criteria for CoRAP substances should not start in 2013 but only later. Compliance Check (CCH) is not a prerequisite for SEv, but ECHA has started targeted CCH for a number of CoRAP substances in order to confirm that standard information requirements for the area of concern would be available before the eMSCA starts the SEv.

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2. Introduction

From 4 to 5 June 2012, the European Chemicals Agency (ECHA) hosted a workshop on substance evaluation (SEv). The aim of the workshop was to discuss and enhance the collaboration between the Member States Competent Authorities (MSCAs) and ECHA during the different steps of the substance evaluation process. The workshop concerned various aspects of the substance evaluation process, such as the submission of the possible draft decision (DD) and SEv report, the decision making process and follow-up, as well as the interaction between the evaluating MSCAs (eMSCAs) and the stakeholders. The collaboration in preparing the update for the next and future Community Rolling Action Plan (CoRAP) was also discussed.

The ultimate objectives of the workshop were:

- to provide recommendations to MSCAs and stakeholders for their interaction and dialogue during the SEv process;
- to provide recommendations to the Registrants for organizing themselves in preparation of the official commenting rounds and the fulfilment of any request of information that may result from SEv;
- to agree on the process to revise the CoRAP selection criteria;
- to agree on how to involve MSCAs in detecting and allocating new CoRAP candidates;
- to collect ideas on the organization of the follow-up after completion of the SEv.

The workshop was attended by sixty participants, including representatives from 24 Member States and Croatia, members of the Member State Committee (MSC), MSC stakeholder observers (CEFIC, CONCAWE, EUROMETAUX, ECEAE), the Commission (DG Enterprise and Industry and DG Environment) and ECHA Secretariat.

The workshop agenda is included in Annex I. The workshop was divided into two main sessions, one on the substance evaluation procedure and one shorter session on the CoRAP update.

After the participants had been welcomed by ECHA's Director of Regulatory Affairs, the session on the SEv procedure started with a series of presentations by representatives from Germany and the Netherlands addressing their first experiences in evaluating the assigned CoRAP substances and the interaction with the stakeholders. Next, ECHA gave several presentations on ECHA's supporting activities for the MSCAs under SEv. The session continued with presentations on the timing of the decision making process, on the meaning of SEv follow-up pursuant to Article 48, and on the reporting about the SEv activity pursuant to Article 54.

In the afternoon of the first day, the session on the CoRAP update took place, with a series of presentations by ECHA. The presentations covered the preparation of the preliminary draft CoRAP, the allocation criteria for distribution of substances among MSs, the revision of the selection criteria (prioritisation) and the performance of compliance check (CCH) of CoRAP substances prior SEv.

Afterwards, the discussion continued in four break-out groups with focus on different topics as follows:

Break out group 1 – From start of evaluation until preparation of substance evaluation report and draft decision
Break out group 2 – Draft decision to be submitted to ECHA
Break out group 3 – Steps after issuing the draft decision to the Registrants
Break out group 4 – New candidate CoRAP substances.

In the morning of the second day the rapporteurs presented the findings and recommendations of each breakout group to the plenary session. The reports were followed by a plenary discussion. Subsequently, ECHA gave two presentations on future developments of the selection of substances for SEv and on the relation between SEv and REACH Regulatory Risk Management (RRM) processes.

The workshop was closed with conclusions and final remarks made by ECHA's Director of Evaluation.

3. Substance Evaluation procedure

3.1 Performing substance evaluation

3.1.1 Member States' feedback on their first experiences

Representatives from Germany and The Netherlands presented their initial experiences in SEv and selection of substances for the CoRAP. They explained how their work is planned and organised nationally. Both MSCAs emphasised the importance of regular meetings between all the national experts involved and the adequate planning of a time schedule for the interaction with Registrants. The following issues were highlighted: difficulty in a) dealing with several registration dossiers for the same substance if the exposure scenarios and estimations differ between dossiers, thus leading to different risks; b) taking into account new information, including updates of registration dossiers, in particular towards the end of the 12 months evaluation period.

The tight timetable of the evaluation phase, 12 months, means that experts have to focus on the key concerns for each substance. It is important that any further information requested will enable a conclusion to be reached for the endpoint of concern. This in turn means that DDs should be very clear and specific in their information requests. The second stage of SEv, once the new information requested is received, could be a lengthy process and MSCAs need to allocate resources to follow-up work. This will occur in parallel with the evaluation of new CoRAP substances in the next years.

Further experiences from MSCAs involved in SEv were discussed in the break out session. It appeared that, at the time of the workshop, the progress of the SEv work on the substances allocated for 2012 was rather variable among MSCAs.

3.1.2 Interaction with Stakeholders

René Korenromp from the Dutch CA presented a thought starter paper on stakeholder involvement in SEv that was prepared in collaboration with other CA representatives as a basis for discussion in the workshop. Several benefits of stakeholder involvement were recognised. It provides an opportunity for the eMSCA to clarify issues in the dossiers leading to better understanding of the concern and a better quality of SEv. It allows Registrants to bring further information to the attention of the eMSCA. It also allows industry to better understand the concerns of the eMSCA. However, it needs to be clear to Registrants what can and what cannot be expected from the interaction with the eMSCA. A common, clear and consistent approach between MSCAs was recommended.

Some specific recommendations about the scope of such interactions were made and these were discussed further in break out group 1. Firstly, the eMSCA should contact the Lead Registrant (LR) as early as possible in the SEv process to start the dialogue. The LR should agree with other Registrants of the substance on who will participate in the interaction. The eMSCA would offer one meeting with the LR to discuss technical issues related to the SEv. At that meeting, the Registrants' representative can ask clarifying questions about the SEv.

The eMSCA in turn can ask for clarification of specific dossier issues such as data interpretation and request study reports / raw data, if necessary. The recommendation was that the LR should coordinate and represent the other Registrants. However, if necessary, also other experts could be nominated to attend the meeting. Meeting participants should be aware of confidentiality issues and CEFIC offered to provide their rules on confidential business

information (CBI) as a guide. Minutes of the meeting should be prepared and shared between participants and with ECHA. It is important for the eMSCA to record in writing how the Registrants' comments were taken into account. Finally, it was recognised that the eMSCA should allocate time for interaction with stakeholders in their planning for SEv work.

In the plenary session, the interaction between Registrants and the MSCAs was discussed further. All the workshop participants agreed that a common approach is needed when interacting with the Registrants to ensure equal treatment of the Registrants. A need for a flexible approach depending on the number of Registrants for the substance under evaluation was recognized. A too rigid approach would be counterproductive.

Industry stakeholders at the meeting strongly supported early interaction between the eMSCAs and stakeholders and emphasised that this should be at the EU-level rather than national level.

Registrants may decide to update their registration dossiers following a meeting with the eMSCA. MSCAs gave a strong message that it would be hard to deal with dossier updates late in the SEv process and urged Registrants to inform the eMSCA as soon as possible when they are planning to update their registration dossiers. Industry stakeholders pointed out that an update does not always have a negative (disturbing) impact on the evaluation. It could be done in agreement with the MSCAs to remove a concern (e.g. during the official commenting period).

ECHA suggested that a news alert is sent after the workshop announcing that MSCAs want to promote interaction with the Registrants. The idea of the news alert was welcomed by the stakeholders, as it would give a signal that the collaboration/interaction is relevant.

It was concluded that it is in everybody's interest that Registrants coordinate among themselves to avoid having contrasting comments from different Member Registrants.

In order to facilitate interaction early in the process, it was agreed to identify the intended eMSCA already at the time the draft CoRAP is published. It was also agreed that the contact details of eMSCAs for the CoRAP related to years 2014 and 2015 will be published.

The role of stakeholders other than the Registrants was not discussed in detail. They should approach the relevant eMSCA if they have relevant information that could be useful for the assessment. As the draft CoRAP and adopted final CoRAP are public, all stakeholders get to know which substances will be evaluated and by which MS. ☐

3.1.3 ECHA's support to the Member States

ECHA gave a series of presentations providing an overview of ECHA activities under SEv.

MSCAs evaluate the substances and interact with the Registrant(s) while ECHA has a coordination role. ECHA functions as a hub for SEv giving administrative support to a number of activities, such as: handling the formal communication with registrants within the decision making process, integrated recording of SEv and RRM activities on CIRCABC (overview table), preparation of guidance and templates, organisation of training and information sessions, monitoring and giving advice during the SEv process, and organisation of workshops. In addition ECHA offers the possibility of a consistency screening of draft decisions before they are sent to the registrant(s) and, likewise any MSCA, can make proposals for amendments to draft decisions in the decision making process. ECHA is committed to provide support in line with the available resources during all phases of SEv.

ECHA gave a presentation to clarify the purpose of Consistency Screening of DDs. The screening will concern the DDs, while the SEv report will be solely considered as background

document and looked at only to identify potential inconsistencies. The DD should be a stand alone document giving reasons for the information requests. Consistency screening is not binding to the MSCA, but it is an offer from ECHA to help harmonising the content and format of the decisions as early as possible. This is not the best way to get legal and scientific advice. For that, eMSCAs are instead invited to contact ECHA earlier in the drafting process. The DD sent to ECHA for consistency screening should be the final version that could possibly pass the consistency screening and be sent to the Registrant without amendments. In order for ECHA to perform the consistency screening, the DD should be received at least two months before the official deadline (28 February 2013 for CoRAP 2012 substances). ECHA will provide feedback within a month and the eMSCA will consider the need to modify the DD. In any case the official submission of the modified DD should take place before the 12 months deadline. The date the DD is submitted to ECHA, and passes the semi-automated validation phase based on business rules, is recorded as the submission date. If ECHA receives many DDs close to the end of December 2012, it might not be feasible for ECHA to perform the consistency screening for all DDs. Therefore, ECHA has recommended the MSCAs to finalise and submit DDs already in early autumn and to indicate the date planned for asking the consistency screening by using the "booking table" available in CIRCABC.

In the break out group, MSCAs appreciated the opportunity for ECHA consistency screening of DDs and the majority of participants expected to use this service in 2012.

Another presentation addressed the information to be included in a SEv IUCLID dossier and how this dossier may be submitted. The format of the SEv dossier is IUCLID version 5.4 (available from 5 June 2012). To support MSCAs in the SEv IUCLID dossier creation phase, aggregated datasets have been made available. These aggregated IUCLID dossiers contain information from all registration dossiers per substance accepted by ECHA until 1 March 2012. ECHA will also regularly report to MSCAs about the receipt of new dossier updates for CoRAP substances. The SEv IUCLID dossier can be based on this initial aggregated dossier. However, it does not necessarily need to be a complete dossier and can be filled in solely for the sections / endpoints that matter in the evaluation. The SEv IUCLID dossier needs to be submitted to ECHA via a web-form. Before acceptance, the received dossier will need to pass a semi-automated validation phase based on business rules, such as the verification of the Legal Entity (LE) submitting the dossier (LE of MSCA), verification of substance information (IUCLID section 1.1 and 1.2), Classification and Labelling information (section 2.1), presence of the SEv report and (if applicable) of a DD. If requested by the MSCA, the dossier will need to pass also the consistency screening of the DD. MSCAs were recommended to activate the email alert in REACH-IT for notification of the receipt / submission date.

Break out group 2 discussed the support provided to MSCAs by ECHA for SEv. The support provided to date, including workshops, legal training, a webinar on IUCLID and instructions and templates, was appreciated and found to be useful. MSCAs indicated that they would like further technical support on IUCLID since they are still learning how to work with the aggregated IUCLID dossiers required for SEv.

In the plenary session, ECHA replied to a number of technical questions, such as how to merge datasets from different MSCAs when SEv is performed jointly, how to use annotations in IUCLID, and the submission of the IUCLID and SEv report to ECHA. It was agreed that for any issue or question regarding IUCLID, MSCAs would contact the ECHA Helpdesk. There was also a discussion and clarification on what type of substance can be evaluated and on what information related to substance identity (SID) should be included in the SEv IUCLID dossier.

3.2 The decision making process and next steps

3.2.1 Content of the draft decision / final decision

ECHA Secretariat gave a presentation that focused on the content of a SEv decision to request further data. Any request for information should be clearly provided via an explicit description of the required data together with the method/criteria necessary to obtain it. Furthermore, the reasoning in a decision should establish a link between the identified concern and the requested information, indicating how the requested data could clarify the concern. The decision is not limited to the initial CoRAP concern. Therefore, any additional concern(s) identified during the SEv must be addressed, together with an explanation, within the first SEv decision.

Care must be taken to ensure that confidentiality of confidential business information (CBI) is not breached. In standard cases where CBI would not be affected, the decision may be addressed to all Registrants of the substance. However, a decision concerning a data request specific to one Registrant (e.g. specific uses and corresponding exposure scenarios) must be processed separately and sent only to the Registrant concerned, in order to respect CBI. In general, the addressees under SEv are the Registrant(s) of the CoRAP substance and equal treatment of all Registrants of the same substance must be maintained. In some cases, DUs may also be addressees, e.g. if they have submitted a DU report for a use not covered by the Registrant and the data requested is specific for that use.

Updates may be submitted as spontaneous updates or in relation to an ongoing interaction between the eMSCA and Registrants. Such updates could be taken into account until the DD is referred to other MSCAs and ECHA, but will not be considered in the decision-making process after this point due to the tight timelines.

MSCAs indicated that they could properly take into consideration only dossier updates made at the latest 1 or 2 months after SEv had started. ECHA acknowledged that MSCAs cannot always take into account new information via updates, but noted that there is a need to allow submission of information that is useful for the evaluation process.

SEv is designed to clarify a suspected risk, using all available and relevant information, in a single process. All the information to be requested should be included in the first decision, because any subsequent DD requiring further information needs to be justified by a change of circumstances or acquired knowledge (Article 47(1)). Such situations would be newly generated data or where the factual basis (e.g. new uses or updated exposure scenarios) changed after the first decision was taken.

In the plenary session, the challenges of handling DDs to be sent to multiple Registrants were highlighted; among these, how to deal with CBI and the possibility to request information from downstream users (DUs). ECHA clarified how to deal with requests of information only relevant for some Registrants. It is necessary to identify who is going to receive the DD if CBI information is involved. In order to avoid disclosure of CBI information issuing separate DDs to different registrants could be necessary. ECHA indicated its willingness to help MSCAs to identify CBI. ECHA indicated that it is possible to address DDs to DUs. Despite some ambiguity in the legal text on this issue, there certainly was an intention by the Legislator to empower ECHA and the MSs to address DUs under recital 66 of REACH.

MSCAs would appreciate advice on requesting exposure information in a DD and information on the typical cost of tests and studies to help consider the proportionality issue when requesting new information. How to request exposure data in a DD will be rather case specific. Only information can be requested in DDs, and no recommendations can be made on Risk Management Measures (RMMs). Also, if an eMSCA disagrees with the DNEL reported by Registrant, the correct DNEL cannot be imposed on the Registrant by a SEv decision. However, in such case the eMSCA could note what it believes is the correct basis for the DNEL in the SEv report and in the conclusion document.

MSCAs also requested further legal advice on Article 46(3) of REACH and in particular on the

calculation of the deadline for concluding on the substance evaluation after the receipt of the requested information.

3.2.2 Timing for a draft decision in the decision making

Timelines and potential bottlenecks of the SEv decision making process were presented. According to Article 46(1) of the REACH Regulation, a DD shall be prepared within 12 months of the publication of the CoRAP. Therefore, the deadline for DDs is 28 February 2013 for CoRAP substances undergoing SEv during 2012.

After formally receiving the DD from the eMSCA, ECHA sends the DD to the Registrant(s) without undue delay. There is no prescribed timeframe for 'undue delay' in the legal text; however, the adherence to a maximum delay of 4 weeks appears to be reasonable. The Registrant has 30 days from receipt of the DD to submit comments to ECHA. ECHA then informs the eMSCA of the Registrants' comments without delay. The eMSCA shall take the Registrants comments into account and may amend the DD accordingly. The eMSCA then notifies the DD, and any Registrant(s) comments, to other MSCAs and ECHA, and gives them 30 days to propose amendments.

At the end of the 30 day commenting period, if the eMSCA received proposals for amendment (PfAs), it shall refer the DD (together with any PfAs) to the MSC within 15 days. ECHA will submit any PfAs to the Registrant(s), who will have 30 days to submit to ECHA any comments. If no PfAs were received then the DD is adopted by ECHA without referral to the MSC. If agreement is sought in an MSC meeting, the eMSCA should be ready to address any immediate changes to the draft decision potentially required during the MSC meeting.

If within 60 days of the date of referral the MSC reaches a unanimous agreement then the decision is adopted by ECHA. If the 60 day deadline is exceeded or if the MSC fails to reach unanimous agreement, ECHA refers the case to the Commission.

A potential bottleneck to the decision making process is the submission of PfAs via REACH-IT to all Registrants. This must be performed in a very short timeframe and may impose a heavy administrative burden on ECHA if large numbers of Registrants are involved. Furthermore, if a substantial number of Registrant(s) comments are submitted to ECHA then this will imply a significant workload to upload them onto CIRCABC for eMSCA assessment, which could lead to potential delays. To reduce this bottleneck, it is suggested that the eMSCA interacts at an early stage with the Registrants, indicating any potential information to be requested and that Registrants try to coordinate their responses to the DD or PfAs in order to reduce the number of responses provided.

It needs to be investigated whether and how the handling of multiple proposals for amendments and the communication to multiple registrants can be eased by the development of IT solutions.

Decision making deadlines are very tight and must be respected, but some flexibility exists after Registrants have commented on the DD. The eMSCA should carefully plan the timing of the MSCA consultation, because it affects at which MSC meeting the DD can possibly be discussed. For CoRAP substances undergoing evaluation during 2012, the eMSCA must initiate the MSCA/ECHA commenting period at specific dates that are related to the already defined dates of the MSC meetings in 2013. Likewise, the eMSCA should make the decision as to whether a case goes for written procedure or not depending on whether the DD appears to require discussion at the MSC or not. Some MSCAs indicated that they intend to review all SEv DDs to learn and share experiences. Due to lack of resources, some other MSCAs may prefer to focus on selected DDs based on their national interest. MSCAs should communicate any concerns and/or additional information on a substance to the eMSCAs early in the SEv process to minimize the need to make PfAs.

3.2.3 Follow up of Substance Evaluation

ECHA gave a presentation on how to use information obtained from SEv. Article 48 of the REACH Regulation states that, once the SEv has been completed, the Competent Authority shall consider how to use the information obtained from this evaluation for the purposes of harmonised classification and labelling, identification of a SVHC, or restrictions. SEv is not a complete risk assessment, but an instrument to gain more information on a substance when it is needed for clarifying potential risks. It can provide an important source of information for concluding on the need of regulatory risk management (RRM). However, just because a substance is subject to SEv does not mean that it will automatically be subject to RRM.

SEv is a lengthy process, requiring a minimum of approximately 2.5 – 3 years to reach the stage where conclusions on the need for RRM can be made. For this reason, long-term vision on what information is considered most important is required. There is no legal deadline for concluding on the need for RRM and the RRM process itself is not an automatic continuation of SEv. The implementation of any RRM such as harmonised classification, authorisation or restriction, requires the eMSCA to start the related procedure under REACH.

One question discussed at the workshop was whether to agree on a submission timeframe for the conclusion document since no legal deadline exists. In addition, the structure/format of the conclusion document has still to be agreed. One proposal was to use the template currently in use for concluding on transitional evaluations originated under the previous NONS Directive and Existing Substances Regulation.

In the break out session the working group indicated that there is the need to further discuss the minimum information to be included in the conclusion document and the relation with the Risk Management Option (RMO) analysis. There is no deadline to issue a conclusion document. How soon the eMSCA can prepare this conclusion document may also depend on the interest to develop a in-depth RMO analysis. ECHA suggested taking a pragmatic approach. The conclusion document needs to be published and can be simple and concise. The parallel production of a RMO document would allow the eMSCA to substantiate further the reasons of the conclusion, it is not compulsory, but is recommended. The eMSCA would not publish the RMO document, which would be restricted to ECHA, other MSCAs and the Commission. The publication of the conclusion document should preferably follow soon after the end of SEv. The RMO analysis can be considered as a working document and as such, can be further developed also after the SEv conclusion is published. No recommendation was made at the workshop on a specific timeline for concluding the process.

Another topic of discussion was the need for enforcement should the registrant not provide the requested information by the deadline set in the SEv decision. Since the registrant(s) could be located in other countries than the eMSCA, the enforcement would require the collaboration among MSCAs. It was concluded that this topic should be considered in the Forum for enforcement. Forum is working on an interlinks project to establish for which enforcement issues the different authorities should contact each other. A workshop is planned with MSCAs on this area, and the issue related to the enforceability of SEv decisions can be addressed there.

3.2.4 Progress report

Article 54 of the REACH Regulation concerns both dossier evaluation and SEv. The current report 'Evaluation under REACH: Progress report'[1] is publicly available and provides

[1] Available at http://echa.europa.eu/documents/10162/13628/evaluation_report_en.pdf

information on the progress made during a given year together with specific recommendations to Registrants. Workshop attendees were invited to provide their feedback on what should be reported on SEv.

For the CoRAP, the report could include statistical information related to the draft CoRAP and final CoRAP updates, e.g.:

- Number of substances per year/CoRAP update
- Number of substances per Member State

The types of initial concerns (e.g. HH versus ENV, uses, exposures, hazards, etc).

Statistical information could also be published for reporting progress on SEv and may include, e.g.:

- Number of draft/final decisions
- Number of evaluations concluded without a DD
- The number/type of studies (including vertebrate or non-vertebrate) requested in final decisions
- Number of second DDs required
- Number of cases requiring regulatory RMMs.

Due to the long timelines involved in SEv, it would be difficult to report some of the above statistics since a decision to undertake RRM could be made several years after the SEv.

Recommendations to Registrants could include messages on how to improve the quality of dossiers by gathering MSCAs' experience of dossiers. The main challenges will be the collection/processing of data in time for drafting the report.

The break out group recommended to include less statistical data and more crucial information for Registrants to improve the general quality of the dossiers.

4. Next and future CoRAP updates

4.1 Selection and allocation of new candidate CoRAP substances

ECHA's presentation focused on the preparation of the next preliminary draft CoRAP list in collaboration with the MSCAs. The basis for selecting potential CoRAP candidates were aggregated datasets (so called Master tables) including relevant administrative, regulatory and hazard information about the substances in ECHA's database. These lists were subjected to IT filtering based on the risk scenarios developed in collaboration with volunteering MSCAs and resulting in 365 pre-selected substances. These substances were manually screened to verify the IT filtered hazard concern and the potential added regulatory value of including the substance in the CoRAP. The manual screening resulted in a list of approximately 70 possible candidate CoRAP substances. The draft justification documents (JDs) for these substances are being prepared. It was also mentioned that the MSCAs can submit their own proposals outside the list. This should have been done by 15 August 2012 to be included in the first annual CoRAP update.

Proposals for the development of criteria to allocate substances for evaluation to MSCAs were received in the Workshop held in January 2012. In general the allocation criteria were seen as a fair and transparent way to distribute the substances among the MSCAs. However, some smaller MSs found that the criteria favoured bigger MSs and clarification was requested. The proposed allocation criteria consider, among others, in which MS the manufacturer(s) or importer(s) of the substance is/are located, the MSs with high exposure of workers/consumers/environment to the substance, and the number of substances already being evaluated by one MSCA.

MSCAs commented on the allocation process emphasising that ECHA should not take initiative in assigning the substances to the MSCAs. Bilateral discussion should solve the problems in the majority of the cases and as a last resort ECHA could organise a meeting for all MSCAs concerned with allocation disputes. On the other hand, some MSCAs were of the opinion that the "first come, first served" principle was not found to be the best way to allocate substances. Therefore, in order to solve any disagreements, ECHA proposed to publish on CIRCABC the on-line "active" preliminary draft CoRAP list for booking the substances of interest. Bilateral discussions between MSCAs should solve most of the possible allocation problems/overlaps. The agreed allocation criteria could be used by MSCAs only as supportive arguments when discussing about competing interests for the same substance. Remaining overlaps could be discussed at the MSC meeting in September/October or in a dedicated webinar, or phone conference. ECHA will prepare draft CoRAP to be sent to MSC and MSCAs by the end of October. In case of any remaining overlaps, the allocation decision would be referred to the MSC (Article 45(3)).

MSs agreed at the plenary session with this proposal. Most of the MSs were in favour to use the overview table of all substances under scrutiny. The table, which also includes potential CoRAP substances and where each Member State can communicate a pre-intention to work on a substance, could help preventing work overlap on the same substance. This is in CIRCABC and can be improved. ECHA pointed out that the webform to notify intention to nominate a CoRAP substance can be used at any time and it does not imply a formal commitment, but rather it means that the MSs has looked at the substance and has considered it for the CoRAP.

The first annual CoRAP update will be adopted and published by 31 March 2013. This a month later than the first CoRAP, published on 29 February 2012. There is no legal deadline for the adoption of the CoRAP update and due to the overlap with the legal deadline for publishing ECHA's Annual Evaluation report (end of February 2013), the CoRAP update will be postponed

by one month. All JDs of the substances in the final CoRAP list to be evaluated in 2013, 2014 and 2015 will be published.

4.2 Revision of the Selection criteria of substances

The legal criteria for the selection of the CoRAP substances are mentioned in Article 44(1) of the REACH Regulation and consist of hazard information, exposure information and aggregated tonnage. In general, the selection should be done on a risk-based approach. The criteria will be revised in collaboration with the MSCAs and accredited stakeholder observers. There will be no CARACAL consultation and the decision on the criteria is taken by the ECHA Executive Director. In addition, any MSs can propose a substance to the CoRAP list outside the selection criteria according to Article 45(5) of the REACH Regulation.

The selection criteria can be refined and developed further at any time, but certain timing in relation to other SEv processes is preferred. It is not foreseen that the refinement of the selection criteria is done annually due to resource constraints, the capacity and development of the IT tools and general stability expectations from Industry. The revision should start more than two years before the CoRAP list is updated based on the new criteria; e.g. if updated criteria should be applied for CoRAP 2014, the process should have started in June 2012 at the latest. ECHA welcomed the views of the MSCAs and stakeholders in refinement and update of the CoRAP selection criteria.

In the plenary session, there was a general consensus that not much work should be put in the revision of the selection criteria at this stage. It was stressed that Article 45(5) of REACH can allow MSCAs to bring other substances outside the criteria. Existing criteria are already flexible and can accommodate additional areas of concern. It was suggested that the tonnage could be split among uses and some risk-based criteria could be introduced. The new pool of substances to be registered in 2013 could fill the capacity for SEv in 2014 and 2015. Therefore, it was felt not justified to change the criteria for such a short time period until those substances are registered.

The conclusion of the plenary discussion was that no update of the selection criteria will be launched, but the strategy to find good CoRAP candidates could be refined.

4.3 Compliance check on CoRAP substances

ECHA gave a presentation to explain how ECHA plans to address possible non compliances in the dossiers containing a substance selected for the CoRAP list. In general, the CCH would target at least the SID and the hazard endpoints related to the initial concern. The idea is to ensure that the dossiers contain sufficient information for MSCAs' evaluation work and that the need for a second round of SEv decisions is minimised. The evaluation would generally focus on the lead Registrant, opt-out and stand-alone dossiers.

5. Future Outlook

5.1 CoRAP Candidate substances from Dossier evaluation

An overview of the different processes and sources through which potential CoRAP substances could be identified in the future was provided. A significant number of substances requiring evaluation can be identified during the compliance check process, and in particular in the frame of the new CCH strategy. The new strategy is based on targeting to Areas of Concern (AoC) and use of IT screening tools. The same IT screening performed to select dossiers for compliance check can be also used to identify CoRAP candidates. Besides ECHA processes, the CoRAP development will also be more interlinked to other EU legislation and international assessment programmes.

5.2 Relation to substances under regulatory risk management

ECHA gave a presentation on the interlinks existing between SEv and REACH regulatory risk management (RRM). The information needs of RRM is one of the basis for identifying candidate CoRAP substances. It was highlighted that the information generated by the SEv is used to decide whether RRM is needed. The RMO analysis can then be used to decide which one is the most appropriate. This is a voluntary tool which should be used as early as possible, even before SEv has started. It can be later revised with more information. The risk management overview table is an existing platform to share information and intentions between authorities and which already includes the CoRAP.

List of Abbreviations

AoC	Area of Concern
CBI	Confidential Business Information
CCH	Compliance Check
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CoRAP	Community rolling Action Plan
CSR	Chemical Safety Report
DD	Draft Decision
DNEL	Derived No Effect Level
DU	Downstream User
ECHA	European Chemicals Agency
eMSCA	evaluating Member State Competent Authority
ENV	Environment
ESR	Existing Substances Regulation
FU	Follow Up
HH	Human Health
JD	Justification Document
LE	Legal Entity
LR	Lead Registrant
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
NONS	Notification of New Substances Regulations
PfA	Proposal for Amendment
PBT	Persistent Bioaccumulative Toxic
QOBL	Quality Observation Letter
RMM	Risk Management Measures
RRM	Regulatory Risk Management
RMO	Risk Management Option
RoI	Registry of Intention
RSS	Robust Study Summary
SEv	Substance Evaluation
SID	Substance Identity
SIEF	Substance Information Exchange Forum
SVHC	Substance of Very High Concern
UVCB	Unknown or Variable composition, Complex reaction products or Biological materials

Appendix 1. – Agenda

Workshop on Substance Evaluation

04 - 05 JUNE 2012

ECHA CONFERENCE CENTRE, ANNANKATU 18, HELSINKI, FINLAND

AGENDA

Monday 4 June 2012 morning session		
8:30	Registration	
Setting the stage Chair Leena YlÄ-Mononen, Director of Evaluation		
9:00	Welcome	Jukka MALM, Director of Regulatory Affairs, ECHA
9:10	Introduction	Leena YLÄ-MONONEN Director of Evaluation, ECHA
Session on substance evaluation procedure Chair Leena YlÄ-Mononen, Director of Evaluation		
9:20	Substance evaluation procedure (feedback to questions): A. How are the Member States planning their work for evaluation of CoRAP substances?: examples from DE and NL (2 x 10 min) B. How to interact with Registrants and other stakeholders? (15 min)	 Leni FINDENEGG, DE Dick SIJM, NL René KORENROMP , NL
9:55	3.1 Discussion & further questions (15min)	All
10:10	C. How is ECHA supporting Member States under substance evaluation? (15 min) D. Is "consistency screening" of draft decisions necessary? (10 min) E. How can SEv IUCLID dossier be submitted and received? What is the content of the dossier? (15 min)	Claudio CARLON, ECHA Claudio CARLON, ECHA Francois LE GOFF, ECHA
10:50	3.2 Discussion & further questions (10 min)	All
11:05	Coffee(15 min)	
11:20	F. What are the key points of a draft decision / final decision? (15 min) G. What is the timing for a draft decision in the decision making? (15 min)	Timo RÖCKE, Legal Affairs Unit, ECHA Charmaine AJAO, MSC-Secretariat, ECHA

	H. What does Article 48 follow up mean? (10 min) I. How to report on the progress made? (10 min)	Marco Valentini, ECHA Pia KORJUS, ECHA
12:10	3.3 Discussion (20 min)	All
12:30	Lunch	
Monday 4 June 2012 Afternoon session		
Session on CoRAP update Chair Leena YlÄ-MononeN, Director of Evaluation		
13:30	Preparation of the preliminary draft CoRAP and Allocation of substances to the MSCAs (30 min)	Marta SOBANSKA, ECHA
14:00	Refinement of the CoRAP selection criteria: preliminary thoughts and roadmap (15 min)	Pia KORJUS, ECHA
14:15	Compliance check of CoRAP substances A. Areas of concern & hazard endpoints (10 min) B. Substance identity check (10 min)	 Paul Kreuzer, ECHA Sanna AIRAKSINEN, ECHA
14:35	Discussion (25 min)	All
15:00	Coffee (15 min)	
Break out group discussion		
15:15	Introduction (10 min)	Marta SOBANSKA, ECHA
15:25 to 18:00	Break out group discussion (2,5 hours) Group 1: From start of evaluation until preparation of substance evaluation report and the draft decision (12 month deadline) Planning and performing substance evaluation Interaction with the stakeholders Group 2: Draft decision to be submitted to ECHA Instructions/support under substance evaluation Consistency screening of draft decisions Submission and content of SEv IUCLID dossiers Content of draft decisions (what to request) Group 3: Steps after issuing the draft decision to the Registrants Timing for handling the draft decision in MSC Follow up under Article 48 Reporting on the progress made Group 4: New candidate CoRAP substances Involvement of Member States in detecting update CoRAP substances Allocation criteria for CoRAP substances and its application	 Chair: René KORENROMP , NL Rapporteur: Louise CONWAY ; IE Chair: Amanda COCKSHOTT, UK Rapporteur: Susan LONDESBOROUGH, FI Chair: Dick SIJM, NL Rapporteur: Tatjana HUMAR-JURIČ, SI Chair: Leni FINDENEGG, DE Rapporteur: Dan MERCKL , UK
19:30	Dinner	
Tuesday 5 June 2012		

Wrap-up Break-out group discussions and Conclusions Chair Leena YlÄ-Mononen, Director of Evaluation		
09:00	Report back from the break-out groups (4x 20 min)	Rapporteurs from 4 break-out groups
10:20	General discussion (60 min)	
11:20	Coffee (15 min)	
11:35	Looking at the future (30 min); a. CoRAP substances from dossier evaluations (15 min) B. Relation to substances under regulatory risk management processes (15 min)	 Claudio CARLON, ECHA Elina KARHU, ECHA
12:05	13. Discussion, comments (25 min)	All
12:30	14. Conclusions and next steps	Leena YLÄ-MONONEN Director of Evaluation, ECHA
13:00	End of the workshop	

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