Workshop on Substance Evaluation

Workshop proceedings
Helsinki, 23-24 May 2011

DISCLAIMER

The opinions expressed in this document may not reflect an official position of the European Chemicals Agency or the organisations that participated in the workshop.

Reference: ECHA-11-R-008-EN_INT
Date: October 2011
Language: EN

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

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

TABLE OF CONTENTS

1 INTRODUCTION

During 23-24 May 2011, the European Chemicals Agency (ECHA) hosted a workshop to discuss the substance evaluation procedure. A section of the workshop was dedicated to the criteria for the selection of substances for substance evaluation and to inform the Member States of the current activities with regard to the development of the draft Community rolling action plan (CoRAP).

The objective of the workshop was to build a consensus view and as far as possible to agree on the most efficient process for substance evaluation.

The workshop was attended by representatives from the Competent Authorities of the Member States (MSCAs) and the members of ECHA's Member State Committee (MSC), the Commission (DG Enterprise and Industry and DG Environment) and the ECHA Secretariat. Althogether 28 countries were represented, including Norway.

The workshop addressed the following topics:

- Preliminary experience from selection and prioritisation of substances for the first CoRAP;
- The procedure for substance evaluation, including organisational aspects and the role of ECHA and the Member States;
- The follow-up to substance evaluation and its link with the identification of risk management options;
- The format and content of the outcome documentation to be prepared by the Member States during the substance evaluation process;
- Capacity-building and collaboration on scientific, legal and technical issues;
- Communication between ECHA and the Member States, and to external audiences.

On the first day of the workshop, after the participants had been welcomed by ECHA's Executive Director, the discussion was initiated by presentations given by Member States and ECHA on all the topics listed above. On the second day, the same topics were discussed in break-out groups followed by a concluding plenary session. This document comprises summaries of the workshop presentations and discussions. It is structured in accordance with the outline of the workshop agenda (see annex).

2 SELECTION CRITERIA (ARTICLE 44) AND CORAP DEVELOPMENT

2.1 Status of the selection criteria

The presentation given by ECHA focused on the selection criteria for the 2012 CoRAP and on the procedure for updating the criteria in coming years.

At the workshop on prioritisation criteria in October 2010[1], ECHA had presented a proposal for criteria to be used for the establishment of the first CoRAP in accordance with REACH Article 44. The initial ECHA proposal had thereafter been amended according to the recommendations made during the October 2010 workshop and based on written comments provided by the Member States. The Member States were supportive about the selection criteria originally proposed by ECHA and therefore no major changes were proposed. However, more emphasis was placed on suspected properties rather than on known properties (e.g. CMR, PBT, sensitising). The cumulative exposure from structurally related substances with critical hazardous properties was included as a new element.

For the current workshop, the revised criteria were presented as one of the background documents. ECHA explained that the revised criteria would be adopted as a decision by ECHA's Executive Director and published. The adopted criteria would be applicable until they are revised[2]. In the presentation, it was pointed out that Member States can propose substances for the CoRAP on the basis not only of Article 44 but also of Article 45(5).

ECHA invited the workshop participants to express their views on the procedure for revising the selection criteria (e.g. how often they think that the criteria should be revised, whether it should be on an *ad hoc* basis or regularly, and when the first revision should take place). As a basis for the discussions, ECHA presented two scenarios describing how the selection criteria could be revised for future CoRAP lists. Both scenarios included the opportunity for MSCAs, MSC stakeholder observers, and (when considered necessary) invited experts to express their opinion on the future selection criteria. The time required for the revision process was estimated to be between six and nine months.

2.2 Update on the prioritisation activities related to the development of the CoRAP

2.2.1 CoRAP development activities

In the October 2010 workshop, ECHA had agreed with Member States to the following stepwise process for the establishment of the CoRAP:

- Step 1: Preliminary identification of candidate substances by ECHA and Member States by 15 April 2011.
- Step 2: Further ranking leading to a preliminary draft CoRAP to be submitted to the Member States by 1 June 2011. The Member States were requested to comment on the selected substances and to indicate the ones they were interested in to evaluate.
- Step 3: Submission of the draft CoRAP to the Member States and the MSC[3].
- Step 4: Adoption of the CoRAP based on the MSC opinion, possibly by 28 February 2012.

[1] Workshop on Prioritisation Criteria for Dossier and Substance Evaluation, 18-19 October 2010.
[2] The workshop concluded that the revised criteria for the first CoRAP could be adopted as proposed by ECHA. The adopted criteria can be found at: http://echa.europa.eu/doc/reach/evaluation/background_doc_criteria_ed_32_2011.pdf
[3] The workshop concluded that the names of the substances included in the draft CoRAP will be made public (See 6.1).

The presentation provided an update of the CoRAP development activity as of the end of May 2011.

Step 1 was completed according to the roadmap. ECHA's selection exercise covered the substances registered under REACH by December 2010. Two routes were used to select substances for substance evaluation. Under dossier evaluation, certain substances were flagged for possible substance evaluation since data gaps and concerns could be addressed only or more efficiently under the substance evaluation process. A second route was the selection supported by IT applications for prioritisation. In total, 50 candidate substances were identified. The Member States also identified approximately 50 suitable candidates for the first CoRAP.

The substances notified by the MSCAs and proposed by ECHA were then addressed in a ranking approach in order (a) to allocate candidate substances on the first, second or third year, or currently exclude them from the first draft CoRAP; (b) to provide supplementary background information that could be used by the MSCAs either to substantiate the justification document for including a candidate substance in the CoRAP, or to reconsider their current priorities for evaluation. The ranking assessment addressed the "priority of concern" and the "regulatory effectiveness". The combination of both assessments indicated whether there may be a need for further pre-examination before starting substance evaluation. This outcome was used to recommend the year for potential inclusion in the CoRAP. At the time of the workshop, the ranking exercise was yet to be finalised. The outcome was provided to the Member States in the first week of June 2011.

2.2.2 IT applications

ECHA presented the IT-based approach, which was used to identify candidates for the preliminary draft CoRAP. The IT applications, which were developed for internal use by ECHA, enable the selection of substances based on the CoRAP criteria including hazard and exposure indicators. Using the IT applications, information regarding the potential for wide dispersive use and exposure, persistence, bioaccumulation, classification and endpoint-specific threshold levels was extracted from the registration dossiers. This information was subsequently combined with information from the public domain as well as with predictions from other available software.

Specific scenarios were developed to select substances fulfilling the CoRAP criteria with focus on CMRs, PBTs and endocrine disruption properties. Additional scenarios were developed for sensitisation and potentially highly toxic substances. The substances that were selected using the IT applications were further manually screened to decide whether or not they should be included in the preliminary draft CoRAP.

2.2.3 Collective experience from Member States

The presentation, given by a representative from Germany, addressed the experience of applying the selection criteria and ranking substances for the first CoRAP, from the viewpoint of the Member States. Furthermore, it addressed several collective ideas regarding which types of guidance and support the Member States would need from ECHA for the execution of their task in the substance evaluation process.

After a short overview of the procedure for substance evaluation, including organisational aspects and the role of ECHA and the Member States, detailed information was given about screening and prioritisation activities from Italy and Germany. The criteria considered were mainly based on aspects related to human health hazards, environmental hazards, tonnage or identified uses. The presentation included two concrete examples of prioritisation of substances for the CoRAP.

The Member States would appreciate expanded and improved support from ECHA in clustering relevant data, for example, by means of the possibility of generic queries over all registration dossiers. This would enable them to receive targeted information which would be

needed to finalise the selection process of individual substances for substance evaluation. The Member States highlighted the necessity of search queries on substances similar in structure and the ability to combine different queries or the combination of different data sources. The suggestion was made to improve REACH-IT, if possible, to be able to identify the most relevant dossiers for a substance and to identify data gaps and discrepancies in the registration data, e.g. different classification and labelling or different DNELs/DMELs of the same substance. One important conclusion of the presentation concerning helpful support was the request for ECHA to give priority in compliance checking to substances proposed for inclusion in the CoRAP.

3 THE SUBSTANCE EVALUATION PROCESS

3.1 Substance evaluation process steps

A speaker from ECHA presented an overview of the substance evaluation process. The participants were reminded that the aim of substance evaluation is to clarify whether a substance constitutes a risk to human health or the environment. The expected outcome of substance evaluation is either a request for further information to clarify the risk, or a conclusion that the risk is clarified and that no further information is needed. If the risk is already demonstrated based on the available information, substance evaluation is not the appropriate tool. In such cases other measures should be initiated (e.g. risk management).

For substances listed on the CoRAP for the first year, the evaluation will start when the CoRAP is published on ECHA's website. The first CoRAP is to be published by the end of February 2012. The MSCAs will have twelve months from the date of publication to prepare the draft decision, if there is a need for further information, or to finalise the evaluation. In case of a request for further information, the decision-making process will be largely the same as for dossier evaluation, with the necessary changes being made. The final decision will be an ECHA decision, except in cases where no unanimous agreement in the MSC is reached. In those cases, the decision is taken by the Commission. The ECHA decision can be appealed through ECHA's Board of Appeal.

After receiving the decision, the registrant(s) will have to submit the requested information, within the timelines specified in the decision. Following this, the MSCAs will have to examine the information received and finalise the evaluation or draft any further appropriate decision within twelve months of the information being submitted. In the latter case, the decision-making process will be repeated again.

In the presentation, it was pointed out that although the registration dossiers are likely to be the main source of information during substance evaluation, the MSCAs can also consider other sources, outside of the REACH regulatory framework. The evaluation should not be a full risk assessment as under the Existing Substances Regulation[4], but focus on the concern(s).

3.2 Legal aspects

ECHA presented its view on some of the legal aspects of substance evaluation, among them the issue of remuneration and ECHA's proposal to perform a consistency check of all substance evaluation draft decisions.

Concerning the transfer of a proportion of the ECHA fee income to Member States for certain tasks identified by the REACH Regulation, the ECHA Secretariat explained the legal basis in Article 74(4) of the REACH Regulation and Article 14 of Regulation (EC) No 340/2008 as well as in the relevant decision of the Management Board MB/20/2009. The necessity to comply with the principles of economy, efficiency and effectiveness was emphasised. It was explained that the Management Board decision explicitly rules out a transfer of ECHA's fee income for work commenced under the previous legislation and that it contains provisions concerning the scale of payments for each Member State. Furthermore, ECHA clarified that an advance payment of up to 25% for Member States can be paid by ECHA on request. The Agency will clarify the individual steps and contractual arrangements before the CoRAP is adopted.

ECHA proposed to perform, to the extent possible, a consistency check for substance evaluation draft decisions during the twelve month evaluation period of Member States. The purpose of the check would be to ensure consistency and legal soundness in decision making. Moreover, the screening would potentially lead to less need for intervention in the

[4] Existing Substances Regulation - ESR (Regulation (EEC) No 793/93)

form of proposals for amendment by MSCAs and ECHA in the official decision-making procedure.

The presentation raised additional issues such as the clarification that dossier evaluation and substance evaluation are independent processes and that compliance checks cannot be regarded as prerequisites to substance evaluation activities. Where appropriate, however, ECHA may perform a compliance check prior to further action. As a limitation to a tiered strategy in substance evaluation provided by the legal text by Article 47(1) of the REACH Regulation, it was stated that after a first information request any other request would need to be based on a change of circumstances or acquired knowledge. This means that elements that could have been addressed already during the first evaluation round would fall outside the scope of a second substance evaluation by law.

Generally, the Member States were reminded of the fundamental principle of proportionality that has to be respected in the decision-making for substance evaluation.

3.3 Outcome documentation of substance evaluation

The presentation focused on the main outcome documents for substance evaluation and on the development of templates. The main outcome documents for substance evaluation are expected to be:

- a draft decision;
- a substance evaluation IUCLID dossier;
- a substance evaluation report;
- a conclusion document on the follow-up risk management actions (Risk Management Options document).

The importance of developing good templates, to achieve an effective, efficient and harmonised process, was stressed. For the workshop, ECHA had prepared drafts of the above-mentioned documents, which were briefly presented during the presentation and further discussed in one of the break-out groups. The template of the draft CoRAP was also presented.

The speaker gave an overview of the role of the different documents within the process. It was mentioned, that the draft decision (if applicable), the substance evaluation IUCLID dossier and the substance evaluation report will be required in order to proceed with the transfer of funds to the evaluating MSCAs. Non-confidential parts of the decision and the substance evaluation report (when finalised) will be made publicly available.

The templates for the main outcome documents should be available by the start of evaluation in early 2012. ECHA will develop them in collaboration with the Member States. It is foreseen that, as much as possible, the available templates used in dossier evaluation and in REACH risk management processes will be used for the substance evaluation process. This is to ensure consistency between the processes and to facilitate the use of the outcome of substance evaluation by other processes.

3.4 Practicalities of substance evaluation

A representative from the United Kingdom gave a presentation (with contributions from France), which highlighted some practical issues that may be encountered during the first experiences with the substance evaluation process. The following issues were identified through practical experience of similar processes or from questions asked, both within the MSCAs and from stakeholders.

Obtaining information on the substances to be evaluated
Registration dossiers will be the main source of current information and at present Member States do not have full access to ECHA's IUCLID database. It was proposed that, until a solution is found, ECHA would provide a bulk download of the relevant dossiers and produce

a summary of information on the registrants/registrations for each substance being evaluated by a Member State.

Scope of an evaluation – targeted evaluation
A substance is selected for evaluation because of an initial concern and the evaluation may focus on clarifying this. In the presentation, it was queried how ECHA interprets Article 47(1) and as such what the consequences of carrying out a targeted evaluation are (see also 3.2).

Link with compliance check
In the presentation, it was pointed out that, ideally, all dossiers should be checked for compliance prior to substance evaluation. However, for the first year of evaluation there will not be time to carry out a thorough compliance check, nor to receive the possibly missing data requested in an ECHA decision. To ensure that substance evaluation is able to proceed, it was proposed that ECHA would do a screen for potential issues and preferably check substance identification. If REACH compliance issues are found during substance evaluation, it was queried to what extent these should/can be addressed given that dossier evaluation is the responsibility of ECHA. It was proposed that guidance would be produced to ensure a consistent approach in cases such compliance check issues were encountered amongst Member States.

Communication with the registrant
During evaluation Member States will need to communicate with the registrant(s) and may need further information, such as full study reports, quickly in order to meet the tight deadlines laid out in the Regulation. It was proposed that ECHA would set up a "communication channel" between the appropriate registrant(s) and the evaluating Member State at the start of the process to facilitate this exchange.

Confidentiality – use of dossier information to produce documents
Information from the registration dossiers will be used to produce evaluation reports, some of which may be made publically available. To ensure that no confidential information is published, it was proposed that ECHA would produce guidance on what information may be included in the evaluation reports. In addition, ECHA would indicate whether information that has been flagged as confidential in the registration dossier had been checked and confirmed by ECHA.

4 CAPACITY BUILDING, COLLABORATION AND COMMUNICATION

4.1 Capacity building, collaboration and communication between the MSCAs and ECHA

The presentation by ECHA highlighted the specific need for effective communication between the MSCAs and ECHA foreseen for the various steps of substance evaluation. It addressed the tools available for communication, coordination and sharing information, in particular the functionalities of the CIRCA system and the possibility to set up specific functional mail boxes.

The presentation also addressed the prime importance of building the capacity of all Member States to carry out the tasks of substance evaluation. ECHA proposed to support capacity building by the following means:

- Training on the legal aspects of substance evaluation draft decisions for the MSCA officers who are responsible for the actual drafting of the decisions, in order to support a common understanding of the legal requirements;
- A contact group focused on legal issues, consisting of experienced MSCA experts supported by ECHA's legal team;
- Support on scientific issues where competence is already available in ECHA or the MSCAs on an *ad hoc* basis;
- IT application demonstrations related to priority-setting and the filtering of substances;
- Training on the QSAR Toolbox.

4.2 External communication

ECHA presented its communication strategy for substance evaluation, which was prepared as a follow up from the October 2010 workshop. The main objective is to make the substance evaluation process better understood by stakeholders and industry. The fundamental premise is promoting transparency on the establishment of the first CoRAP and on the outcomes of the evaluation activities. The main message to stakeholders and industry is that they will be kept informed and involved in the substance evaluation process.

The Agency has already taken a pro-active approach and published a fact sheet on substance evaluation. The great number of downloads of the fact sheet, alongside the pressure from NGOs for an ambitious substance evaluation programme under REACH, confirms the growing interest in the topic.

Considering the key role of the Member States in the substance evaluation process and the need to interact with stakeholders and NGOs, ECHA has planned to stage its communication actions before the adoption of CoRAP around the Stakeholders Day and the meetings of the MSC. Discussions during the workshop challenged the participants' commitment to transparency by advancing the idea to publish the draft CoRAP at the same time as it is submitted to the MSC. The participants agreed on publishing the list of the substances proposed in the draft CoRAP and the year in which they will be evaluated, while the names of the evaluating Member States will be published only when the first CoRAP is formally adopted. ECHA is also planning to communicate the first CoRAP launch widely, in cooperation with the Member States, accredited stakeholders and the Risk Communication Network. Following the launch of the first CoRAP, it will be necessary to extend the scope of the communication action plan in order to address the registrants themselves as a specific target group and to raise awareness among the general public on the new knowledge gained through the substance evaluation process.

Striking the best balance between the underpinning principle of transparency and the need for confidentiality was a major theme in the discussion on external communication.

5 BREAK-OUT GROUP DISCUSSIONS

5.1 The procedure for substance evaluation

The following is a summary of the conclusions and proposals by two groups separately discussing how to optimise the procedure for substance evaluation.

Proposals for improving the procedure for substance evaluation
In order to facilitate screening of substances for future CoRAP lists, one of the groups proposed among other things that representatives from the Member States would convene within ECHA premises and collaborate with ECHA staff. A major proposal for supporting the substance evaluation by the other group was that a "Substance Contact Officer" based in ECHA would coordinate the contact between the Member States and ECHA during the evaluation of a specific substance.

The groups concluded that further clarification from ECHA was needed on aspects such as:

- the possibility of Member States to request the registrant to provide information pursuant to Article 36 of the REACH Regulation;
- the implications of targeting the evaluation to specific endpoints or issues of interest;
- the security rules and transfer of funds when the MSCA outsources evaluation tasks;
- confidentiality of information in the registration dossiers (what in the registration dossier should be considered confidential?).

Links to dossier evaluation
Both groups concluded that compliance checks should, ideally, be completed before the start of substance evaluation. It was, however, clear to the participants that this will not always be possible during the first years of the substance evaluation process. If a registration dossier for a substance to be evaluated contains a testing proposal, the decision on how to proceed should be taken on a case-by-case basis, taking into account whether or not the testing proposal is linked to the concern identified for this substance.

Ensuring a harmonised approach and legal soundness of the draft decisions
The proposal that ECHA would perform a consistency screening of all draft decisions was supported by the break-out groups. The group members also welcomed other types of support for the preparation of high quality draft decisions, such as:

- informal communication between the Member States and ECHA throughout the process;
- training, including a possibility to work on case studies;
- consultation with scientists from ECHA;
- documents on frequently asked questions and recurring issues;
- good templates for outcome documentation.

Recommendations for risk management actions
When the registrant(s) have submitted the requested information, the evaluating Member State should give its recommendation for conclusions on the follow-up risk management actions. As the timeline for this process step is not specifically defined by the REACH Regulation, it was taken up for discussion at the workshop. The break-out groups proposed that the evaluating Member State should give its recommendation for conclusions as quickly as possible or within approximately six months of the finalisation of the evaluation.

Selection criteria
Only one of the two groups had time to address the questions regarding the selection criteria. This group agreed that the first CoRAP selection criteria should be adopted as a decision by the ECHA Executive Director as proposed by ECHA. The break-out group

suggested that the criteria should be revised for the first time for the 2014 CoRAP and supported the idea that the MSC stakeholder observers and invited experts should also be heard in the process, although not requested by the legislation.

Allocation of orphan substances
As the evaluation is the task of the Member States, substances identified as candidates for the first CoRAP by ECHA need to be allocated to the Member States. The group supported ECHA's suggestion that the Member States should name their preference and priorities for CoRAP candidate substances to which no Member State was yet assigned.

5.2 Outcome documents/templates and external communication

One break-out group discussed the outcome documentation to be produced during the process of substance evaluation as well as issues related to confidentiality and to communication with registrants.

Outcome documents and templates
The group addressed in particular the substance evaluation report format and the draft decision template, which had been prepared by ECHA. The documents were on the whole supported. The group nevertheless gave several detailed proposals for amendments of the substance evaluation report, which ECHA will use for developing the format further. In the future, ECHA should be responsible for updating the templates and when doing so invite the Member States to provide written proposals for amendments.

Publication of the outcome documents and the draft CoRAP
As decided by the ECHA Management Board, non-confidential versions of the decisions on requests for further information will be made publicly available to promote transparency of the process. The same is envisaged to apply to the evaluation reports. The group requested ECHA to clarify how the protection of confidential data should be ensured. The group furthermore discussed and supported the proposal that the names of the substances included in the draft CoRAP would be made public.

Call for information from registrants
The group proposed that a call for information could be sent to all registrants of a specific substance as soon as this substance is placed on the CoRAP list. The purpose of this call would be to avoid requesting unnecessary tests by having all the relevant data available, which has possibly not yet been included in the registration dossiers.

5.3 Capacity building, collaboration and communication with ECHA and the MSCAs

One break-out group discussed the issue of how to best build the capacity of the Member States for their tasks in substance evaluation and how to facilitate collaboration and communication between ECHA and the MSCAs.

Support for the MSCAs by ECHA
The group concluded that priority should be given to learning from the experience of ECHA from dossier evaluation and to guidance for the use of IT-tools. Other types of useful support include guidance on working procedures and preparing draft decisions, and lessons learnt by the Member States when selecting substances for CoRAP and when assessing substances under the previous chemicals legislation.

Collaboration and communication
The group were in favour of the idea that two or more Member States could share the evaluation of one substance. This possibility would facilitate capacity-building and therefore be of advantage to the process of substance evaluation.

Communication between the Member States and ECHA

The group supported a proposal by ECHA to use the newsgroup function on CIRCA in order to facilitate communication between the Member States. The group proposed that the newsgroup could include specific folders for specific types of issues and for each substance.

The group concluded that it would be useful if a peer review of the evaluation conclusions could be made upon request by the Member States and that it should be the task of ECHA to facilitate such a review.

6 CONCLUSIONS

6.1 Selection criteria (article 44) and CoRAP development

- The use of the refined selection criteria for the development of the first CoRAP was supported by the workshop participants. The selection criteria were adopted as a decision by the ECHA Executive Director and published on the ECHA website after the workshop[5].
- The selection criteria and their application shall be refined in the coming years as ECHA and the Member States gain experience with the first evaluations and along with further development of IT approaches for the prioritisation activity. ECHA will regularly report on the implementation of the criteria.
- The names of the substances included in the draft CoRAP will be made public. The final CoRAP will be published with the name of the evaluating MSCA and a general description of the reasons for concern.
- ECHA will explore the possibility for an exchange of experience between ECHA and MSCA experts in common working sessions at ECHA premises.
- ECHA will continue to refine the IT searching tools and address open questions regarding IT access and data protection.
- At the moment of the workshop, it was acknowledged that a lower than expected number of candidate CoRAP substances had been identified and that a relatively low number of MSCAs plan to take on evaluation tasks during the first year of substance evaluation. ECHA understands the need to build up experience and capacity and will take this issue to discussion at a higher level.
- It was agreed that the MSCAs should indicate their preference for the substances proposed by ECHA. If two or more MSCAs express an interest in evaluating a specific substance, ECHA will facilitate discussions for reaching agreement between the respective MSCAs.

6.2 Substance evaluation process

- The participants concluded that compliance checks of the relevant dossiers should preferably have been conducted prior to the start of substance evaluation. It was however acknowledged that this will not be the case for the first CoRAP years. If the relevant dossiers contain testing proposals, this should be dealt with on a case-by-case basis.
- It was emphasised that the grounds for concerns for placing a substance on the CoRAP are the initial concerns, and that they should not limit the assessment. It was however acknowledged that targeting of the substance evaluation can be necessary as the resources are scarce and the evaluation process is limited to only twelve months.
- The Norwegian CA volunteered to take the question of ensuring confidentiality when outsourcing substances to consultants outside the MSCAs to the Security Officer's network. It was agreed that until the confidentiality aspect has been fully clarified, confidential data can be handled only within the premises of the MSCAs and ECHA.
- The MSCAs were reminded that the framework contract and service request, which set the basis for the agreement between ECHA and the MSCAs on remuneration,

[5] http://echa.europa.eu/doc/reach/evaluation/background_doc_criteria_ed_32_2011.pdf

need to be settled before the publication of CoRAP. ECHA will clarify the timing of the reimbursement, including the option of 25% pre-financing.

- The MSCAs supported ECHA's proposal of performing a consistency screening of all substance evaluation draft decisions, subject to available resources.
- The formats and templates for the substance evaluation outcome documentation presented by ECHA were, on the whole, supported by the workshop participants. Several good suggestions for improvement of the substance evaluation report format were proposed. This template will be refined based on these suggestions and further written comments by the MSCAs.
- ECHA will provide further clarification on certain legal and procedural issues, such as:
    - the practical implications of REACH Article 47(1);
    - ensuring confidentiality of data included in the substance evaluation outcome documents;
    - the use of REACH Article 36(1) for requesting full study reports;
    - whether the CoRAP could contain more than one entry for a specific substance in case the substance has several reasons for concern;
    - the application of the 12-month deadline for preparing a draft decision.
- ECHA plans to organise another workshop on substance evaluation in the first half of 2012 for further discussion on legal and practical aspects of the substance evaluation process.

6.3 Capacity building, collaboration and communication

- The MSCAs expressed their interest in training on legal, scientific and IT-related issues as well as in various types of supporting documents. The support will be provided by ECHA according to demand and capacity.
- The use of newsgroups in CIRCA and a common knowledge database for collaboration and communication between ECHA and the MSCA will be considered further.
- A possible call for information to registrants and the public as soon as a substance is placed on the CoRAP will be considered further.
- ECHA may offer support to MSCAs requesting registrants to provide information on available studies.
- The Member States, ECHA and the Commission will coordinate activities for raising awareness of substance evaluation among registrants and governments.

Annex – Workshop agenda

Workshop on Substance Evaluation

23-24 May 2011

ECHA Conference Centre
Annankatu 18, Helsinki, Finland

Draft Agenda

Monday 23 May 2011

From 8.30	Registration
9.30 – 09.50	**1 A.** Welcome *Geert Dancet, Executive Director (ECHA)* **1 B.** Chair: Leena Ylä-Mononen, Director of Evaluation (ECHA) Objectives of the workshop: Why are we evaluating substances?
SESSION 1 - SELECTION CRITERIA (ARTICLE 44) AND CORAP DEVELOPMENT	
09.50 – 11.00	**2 A**. Status of selection criteria (15 min) - Process of adopting the selection criteria - Timing for further refinement of the criteria *Pia Korjus (ECHA)* **2 B.** Update on the prioritisation activities related to the development of the CoRAP (30 min) - How the criteria and tools were used by ECHA - Notifications from the MSCAs (also Article 45(5)) - Next steps towards the first CoRAP; ranking *Claudio Carlon (ECHA)* *George Fotakis (ECHA)* **2 C**. Collective experience from MSs (25 min) - How did we find our candidate substances; From the national concerns to CoRAP *Gudrun Walendzik (DE)*
11:00 – 11.20	*Coffee break*

11.20 – 12.30	**3. Plenary discussion**
12.30 - 13.30	*Lunch*
SESSION 2 - SUBSTANCE EVALUATION PROCESS	
13.30 – 14.40	**4 A.** Substance evaluation process (30 min) - Necessary process steps with outcome documentation - Role of ECHA *Timo Röcke (ECHA)* *Wim De Coen (ECHA)* **4 B.** Outcome documents of substance evaluation *(20 min)* *Evelin Fabjan (ECHA)* **4 C.** Practicalities of substance evaluation; considerations from the Member States *(20 min)* *Amanda Cockshott (UK)*
14.40 - 15.00	*Coffee break*
15.00 - 16.00	**5. Plenary discussion**
SESSION 3 - CAPACITY BUILDING, COLLABORATION AND COMMUNICATION	
16:00 – 16:30	**6.** Capacity building, collaboration and communication regarding substance evaluation (30 min) - How to share best practices - How to communicate efficiently between the players and outside world *Paul Kreuzer (ECHA)* *Virginia Mercouri (ECHA)*
16.30 - 17.30	**7. Plenary discussion**
17.30	*End of Day 1*
19.30	*Workshop Dinner*

Tuesday 24 May 2011

DISCUSSION IN BREAK-OUT GROUPS	
9.00 – 9.10	**8.** Introduction to break-out groups *Claudio Carlon (ECHA)* **Topic 1) The procedure for substance evaluation (2 groups)** - suggestions for ensuring efficient, transparent and workable process steps - the evaluation part of the substances and the decision making part of the draft decisions *Chair 1a Majella Cosgrave, IE* *Rapporteur 1a Marc Pritzsche, DE* *Chair 1b Rene Korenromp, NL* *Rapporteur 1b Amanda Cockshott, UK* **Topic 2) Outcome documents/templates and external communication (1 group)** - consistency in the reporting and preparing outcome documents, - further guidance - communication to the public and registrants of the results of substance evaluation *Chair 2 Cecile Michel, FR* *Rapporteur 2 Tatjana Humar-Juric, SI* **Topic 3) Capacity building, collaboration and communication with ECHA and MSCAs (1 group)** - effective sharing of the lessons learned - open and transparent communication about the work on-going and achievements gained between MSCAs and ECHA *Chair 3 Leonello Attias, IT* *Rapporteur 3 Magdalena Balicka, PO*
9.10 – 12.00	**9.** Discussion in break-out groups
	Coffee available from 10:00 to 11:00
12.00 – 13.00	*Lunch break*
13.00 – 14.00	**10.** Discussion in break-out groups (preparation of recommendations of the group)
14.00 – 15:00	**11.** Wrap up of the break-out groups discussions in plenary
15.00 – 15.20	*Coffee break*
15.20 – 16.40	**12.** Wrap up of the break-out groups discussions in plenary
16.40 – 17.00	**13. Conclusions**
17.00	**End of the Workshop**