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Workshop on dossier and substance evaluation

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Workshop on dossier and substance evaluation - proceedings

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TABLE OF CONTENTS

1. INTRODUCTION

From 31 January to 1 February 2012, the European Chemicals Agency (ECHA) hosted a workshop on dossier and substance evaluation. The aim of the workshop was to align and develop a common understanding on the main principles applied in the dossier evaluation, the roles of different actors and the future strategy for compliance check. The ultimate purpose was to identify areas for further improvement in order to effectively and efficiently cope with increasing workloads.

The workshop was attended by representatives from the competent authorities of the Member States (MSCAs) and the members of the Member State Committee (MSC), the Commission (DG Enterprise and Industry and DG Environment) and ECHA.

The workshop was divided into two main sessions, one on dossier evaluation and one shorter session on substance evaluation.

After the participants had been welcomed by ECHA's Executive Director, the session on dossier evaluation was kicked off by ECHA with a presentation addressing the framework and principles on dossier evaluation. Further on, ECHA gave several presentations on the future compliance check strategy developed in order to support the long term strategic objectives of REACH, the current experience with dossier evaluation and proposals to improve the efficiency of evaluation processes. The session continued with presentations of representatives from Germany, the United Kingdom and Denmark who presented their perspectives on dossier evaluation, the resources available and difficulties encountered, as well as suggestions on how to improve efficiency from their side.

In the afternoon of the first day, four break-out groups were formed to continue the morning plenary discussions with focus on four complementary topics as follows:

Break-out group 1 - Targeted compliance checks: higher tier human health endpoints and issues of sequential testing

Break-out group 2 - Sequential testing strategy: higher tier environmental endpoints

Break-out group 3 - Future compliance check strategy

Break-out group 4 - How to deal with proposals for amendments and comments in order to improve the dossier evaluation process

The tasks of the break-out groups were to reach agreement and answer the pre-defined questions considering the information provided in the background documents and previous presentations, as well as draw some recommendations and conclusions to be presented to the plenary session. It should be emphasised that while groups 3 and 4 addressed general and principle issues of the topics mentioned, groups 1 and 2 addressed more specific human/environmental health issues in relation to both main topics, i.e. improving efficiency and the new compliance check strategy.

In the morning of the second day, the rapporteurs presented the findings of each break-out group to the plenary session. The reports were followed by a plenary discussion. The session on dossier evaluation was closed with conclusions and final remarks made by the ECHA Director of Evaluation.

The afternoon of the second day was devoted to substance evaluation. This session aimed to inform and get feedback for developing the updates of the Community Rolling Action Plan (CoRAP) and substance evaluation procedures as well as on providing ECHA support to the Member States. The best practices from the dossier evaluation process recommended to be implemented in substance evaluation too.

ECHA gave two presentations addressing the adoption of the first CoRAP and the roadmap for the CoRAP update and some practical/administrative issues around further organisation of the substance evaluation process and collaboration between ECHA and

the Member States in this process. After plenary discussions on the issues presented, the workshop was concluded by ECHA's Director for Evaluation.

2. DOSSIER EVALUATION

This session was focused on the future challenges of the dossier evaluation process and more specifically on the high output expected, ensuring sufficient and adequate information on substances for adequate hazard and risk assessment, and avoiding unnecessary animal testing. This requires reaching unanimous agreement on scientifically and legally sound decisions and ensuring transparency of the overall process.

The presentations and break-out groups under this session addressed two main topics:

- Improving the efficiency of dossier evaluation, especially with regard to the decision making process
- The future strategy on compliance checks

The presentations and discussions have been grouped and summarised below according to these two main topics.

2.1 Improving efficiency of the dossier evaluation process

The session was introduced by a general presentation outlining the current framework and principles applied in dossier evaluation according to agreements reached at previous evaluation workshops. Participants were also provided in advance with a background document addressing the principles applied in both dossier evaluation sub-processes: **compliance checks** and the examination **of testing proposals**. The presentation summarised the information in the background document and addressed the scope, the principles to be applied and the implementation approach for both sub-processes. It was acknowledged that the framework and principles applied in dossier evaluation are gradually evolving based on the experience gained. In particular, unanimous agreements by the MSC or the Commission decisions on individual draft decisions may necessitate changes to the approach. For this reason, the current framework is subject to further refinement and changes.

2.1.1 ECHA's perspective on dossier evaluation

The ECHA secretariat presented the current experiences on dossier evaluation and addressed the measures already taken for improving efficiency. Further on, ECHA made some proposals aimed at improving efficiency to better cope with the increasing workloads.

The current experience on dossier evaluation outlined the status of evaluation, the decisions taken so far and presented a quantitative analysis of proposals for amendments and comments submitted during the decision making process. It was stated that the number of draft decisions which require referral to the MSC is higher than foreseen; currently, about 40 % of the draft decisions received proposals for amendments from MSCAs and hence required referral to the MSC.

According to the analysis made by the ECHA secretariat, the number and type of proposals for amendments reflect differences in both legal and/or scientific interpretation of the REACH requirements, as well as the lack of agreed policy approaches on endpoints and differences in MSCAs national policy lines. One of the recurring themes in the proposals for amendments is sequential testing in relation to information requirements and classification and labelling (C&L). There are also a relatively high number of proposals for amendments expressing agreement with ECHA's draft decision; although appreciated, they lead to additional work during the decision making and should thus rather be avoided. Some of the proposals for amendments could have been avoided if

informal interaction had occurred (e.g. some proposals for amendments have been formulated as questions). It has also been emphasised that prior communication and agreement led to speeding up the process, e.g. draft decisions handled through written procedure.

It was further stated that, in general, the decision making process has been functioning well so far as all draft decisions were processed within the legal deadlines. However, due to heavily increasing number of draft decisions, there is a need for further improvement. This requires developing a common understanding on policy approaches and a greater level of informal communication between MSCAs and ECHA during the 30 day MSCA commenting period.

Further on, the ECHA secretariat looked into the current and future workload for dossier evaluation. It was stressed that as of MSC 23, the workload will increase at a fast rate. ECHA has already undertaken some measures to increase efficiency: development of standard texts for testing proposal draft decisions (DDs), increased communication with the registrant prior to and during the 30 day registrant commenting period, management of the dossier numbers and "types of DDs" to be sent to MSCAs, and extensive use of previous MSC considerations and agreements in the decisions taken.

Participants were presented with a set of proposals for further improving efficiency, addressing several stages of the decision making process, i.e. before, during and after the 30 day MSCA commenting period. The aim of further improving the efficiency is to maintain the current level of quality of decisions while increasing the output. Participants were requested to further discuss the options presented (during the break-out groups) and formulate some recommendations.

The last presentation of the ECHA secretariat on this topic focused on the developments of the decision making process. The roles of the different players during the decision making process (ECHA, MSCAs, the MSC, registrants) and the differences compared to the previous legislation were underlined. It was stressed that the aim should be to avoid the 'ping-pong' effect i.e. a continuous discussion between authorities and registrants which does not lead to a conclusion in reasonable time.

The presentation also addressed some recent developments within the decision making process: potential rejections of testing proposals, termination of testing proposals, splitting draft or final decisions (non-unanimous agreement of the MSC of the Extended One Generation Reproductive Toxicity Study), and accepting the use of international test methods not yet indicated in the test methods regulation (under specific circumstances).

2.1.2 Member States perspective on dossier evaluation

The session continued with three presentations from Member States (the United Kingdom, Germany and Denmark) which presented the view of the Member State Competent Authorities on the decision making process. The following issues were addressed:

- Internal organisation of the competent authority in relation to dossier evaluation and the decision making process, i.e. MSCA's commenting period
- The role of Member States during the decision making process and how the role has changed comparing to the previous legislation
- Current experience regarding collaboration with the ECHA secretariat
- Difficult cases handled so far and Member State views on topics such as exposure assessment, avoidance of animal testing in relation to testing proposals and compliance checks, etc.
- Resource issues and suggestions for improving efficiency from the MSCA's side in order to cope with the increasing workload

Member States outlined some of the technical difficulties faced, e.g. statistics provided by ECHA are difficult to follow and do not match with their own statistics, problems with downloading the necessary IUCLID files, problems in identifying the lead registrant in REACH IT, difficulties in matching the registration number with the respective dossier.

It was also emphasised that the approach followed during the commenting period had been changed and would need to be further adapted in order to cope with the increasing workload. The focus during the commenting period will change from reviewing the whole dossier to reviewing only the issues in the draft decision or the dossiers of higher concern, or the draft decisions on registrations from the own country dossiers. Furthermore, it was stated that in order to carefully plan their resources, Member States would need feedback from ECHA on the exact number of draft decisions per commenting period.

Another issue raised was the process of follow up to dossier evaluation: it has been observed that in some cases, registrants did not update their dossier, although the deadline has passed and no reason was provided. Member States would need concrete feedback from ECHA for possible enforcement actions.

Plenary discussions

Following the presentations, the participants were invited to express opinions on the presentations, processes and other topics of general interest. The main topics for discussion concentrated around the following issues:

What is the opinion on the decision making process of those MSCAs that generally do not submit proposals for amendments:

The main reason for not submitting proposals for amendments was that MSCAs agreed with the evaluation of ECHA and did not see the need to propose amendments. Another reason mentioned was that certain Member States are confronted with resource constraints and may rather concentrate on the draft decision and cannot check the rest of the dossier.

What is the reason for submitting proposals for amendments:

Some Member States expressed the view that in some cases they wanted to pass certain messages to registrants in order to improve the quality of dossiers and hence avoid further testing. However, due to the time constraints of the decision making process, ECHA (and the other actors in this process) cannot consider dossier updates made after the draft decision has been referred to the MSCA. Hence, passing these messages to the registrants was considered to be problematic and redundant as this could mislead the registrants to think that updating at the decision making stage would be taken into account.

In this context the workshop participants were reminded that the role of proposals for amendments is not to give advice to registrants. REACH clearly states the roles of the different actors and thus ECHA and the Member States should avoid as much as possible to act as "consultants" for the registrant.

Other Member States stated that they submitted repeated proposals for amendments in order to emphasise their opinion and make sure that the respective cases would be discussed during the MSC meetings. Another reason for submitting proposals for amendments was to underline the need to consider the most recent scientific developments, such as in the case of the newly adopted OECD guidelines for reproductive toxicity and mutagenicity. It was also stressed that the guidance documents may sometimes become outdated in light of new scientific developments and registrants should be requested to perform certain tests with the newly available methods. ECHA however reminded that the test method regulation and guidance documents are the principal reference with regard to testing under REACH, whereas Art.

13(3) gives ECHA the possibility to recognise new test methods that adequately address the REACH information requirements.

The type and number of proposals for amendments show that MSCAs do not always receive proper feedback from the MSC meetings, therefore better coordination between the MSC member and the respective MSCA representative, and their supporting experts, is desirable.

During the discussions, it was mentioned that the MSC secretariat initiated a project on further developing the MSC manual of decisions and that the MSC members were invited to volunteer for this project. The manual of decisions will take stock of the agreements made on previous decisions, policy and scientific lines taken. The manual should be used by all actors, ECHA, MSCA, MSC, and would eventually contribute to increasing efficiency of the process and decreasing the number of proposals for amendments submitted.

Rejection of testing proposals

Some Member States expressed the opinion that in their view, the REACH requirements set in the Annexes should be seen as minimum information requirements. Therefore, there is no reason to reject testing proposals which go beyond the formal information requirements. However, other Member States stressed that informal interaction with the registrant (before a draft decision is sent) would be beneficial to understanding that no mistake has been made when submitting a testing proposal. Furthermore, it would avoid unnecessary animal testing and reduce the costs for both, registrant and authorities.

Other issues addressed:

Involvement of the members of the joint submissions in the decision making process

Based on feedback from industry, it has been suggested that members of the joint submissions should be made aware of the draft decisions. This issue has been looked into by the ECHA secretariat. It has been stressed that due to efficiency considerations, the draft decisions on testing proposals are addressed only to the lead registrant. ECHA is analysing how it can organize that decisions on compliance checks which deal with the joint part of the dossier may be shared with members of the joint submission.

Further on, the session on dossier evaluation continued with a one hour presentation-training by the ECHA Legal team. This presentation was meant to introduce the MSCAs to the principles applied in drafting evaluation decisions, in order to better understand the reasoning behind the dossier evaluation decisions, which can be further applied for drafting future substance evaluation decisions. It has been stressed that a more comprehensive training targeted to drafting decisions for substance evaluation will be provided by ECHA at a later stage, during spring 2012.

2.1.3 Break-out groups – recommendations and conclusions

The discussions on the ways to improve efficiency continued in the break-out groups. Three break-out groups were dealing with this topic. Break-out groups 1 and 2 addressed scientific challenges for higher tier human health and environmental testing and sought agreement on some lines to take. Break-out group 3 looked into more general issues concerning proposals for amendments and comments and how to deal with them in order to improve efficiency.

The following general conclusions could be drawn from the break-out group feedback reports.

a) Improving efficiency of the dossier evaluation process

Solve administrative issues

A number of administrative issues need to be solved on ECHA's side in order for the Member States to make more effective use of the MSCA 30 day commenting

period: solve the problems with the downloading of IUCLID files; provide MSCAs with an aggregated form of the draft decisions for faster screening, selection and prioritisation of draft decisions (DDs); this list should preferably contain endpoints/issues, country, tonnage band, C&L, CAS number, test guidelines.

Increase communication between the main actors

Increased communication between ECHA – MSCA – MSC is one of the important factors for ensuring efficiency. Within ECHA, a single point of contact with the Evaluation units should be established. Within the MSCAs, the country coordinator will identify their expert for technical discussions. An increased interaction between ECHA and the MSCAs should take place during the commenting period to achieve more clarity and understanding of the cases and eventually lead to less proposals for amendments. For example, if the MSCA is unsure whether their concern warrants a proposal for amendment, they may first contact ECHA and then decide to act.

It is also necessary to increase interaction between MSCAs (and their supporting experts) and the MSC member; the outcome of each MSC meeting needs to be properly communicated to the MSCAs and the agreements made at MSC level should be considered before a proposal for amendments is submitted

Proposals for amendments

It has been agreed that the aim of proposals for amendments is to perform a quality check on ECHA's draft decision. Therefore, it is desirable and possible to reduce the proportion of proposals for amendments.

It was tabled and discussed that a good quality proposal for amendment should clearly and concisely state what is required from the registrant and why it is required. Member States are encouraged to submit proposals for amendments in the form of textual changes for the different sections of the draft decisions. This further minimises the need for '*in situ*' writing during the MSC-meeting, decreasing the potential of 'drafting' mistakes under time pressure.

It was agreed that for the compliance checks targeted to substance identity, no proposals for amendments should be submitted; on its side, ECHA will ensure that such cases are properly flagged in order to avoid potential misunderstandings.

If the MSCA consider a particular endpoint/issue as a priority, they could submit proposals for amendments to encourage discussion at the MSC and to achieve agreement on the endpoint/issue.

Principle issues or new science developments may require significant discussion to align on an agreed approach. For such issues it may be appropriate and necessary to establish expertise driven working groups which report back to the MSC meeting where a general agreement on the legal and scientific approach has to be reached.

Comments

It was mentioned that some Member States submitted comments since they thought that these are submitted to the registrant in order to improve the quality of their registration dossier. However, ECHA clarified that according to the procedure and REACH obligations, no comments are forwarded to the registrant, only proposals for amendments.

In order to improve efficiency, ECHA will not respond any longer in writing to the received comments in the RCOM. These comments will be captured in Odyssey (internal ECHA tool used in the evaluation workflow) for future use when the specific dossier is revisited again (e.g. in a future compliance check). An analysis will be made if and when time allows determining if general trends or priorities can be established and acted upon.

It was further stated that MSCA's focus should be on proposals for amendments, and that when a Member State wants to raise an issue for discussion at the MSC meeting, it should be clearly indicated as the aim of the comment so that ECHA can act upon this accordingly.

b) Testing strategy for higher tier human health endpoints

In general, it was agreed that for both compliance checks and testing proposals, ECHA should not take responsibility for choosing the order of the tests but let the registrant decide. However, sufficient time for sequential testing should be provided as this would help avoiding unnecessary animal testing. Consequently, parallel testing for related endpoints should be avoided. Where appropriate, the (draft) decision could include reminders about the potential for column 1 and 2 adaptations; this approach has already been implemented for testing proposals and should be extended to compliance checks.

It was also agreed that in general, the draft decision should rather contain requests for further tests since this brings more clarity, i.e. registrants know what they have to deal with. A request for further information could simply result in the registrant filling in the dossier with a poor adaptation. However, the registrant may decide to fulfil the endpoint with an adaptation (Column 1 or 2, or Annex XI). ECHA evaluates the information provided by the registrant during the follow-up and will then be able to decide whether the information submitted is sufficient.

c) Environmental testing strategy in the context of testing proposals

Testing strategy for long-term aquatic endpoints

A way forward for dealing with the testing proposals for long-term *Daphnia* and fish testing was proposed (see the table below). The table has two entries: i) the registrant's TP and ii) the relative sensitivity of *Daphnia* and fish.

There was no unanimous agreement with regard to dealing with testing proposals for long-term aquatic testing: some participants expressed the opinion that testing proposals submitted should only be rejected in very rare cases; however, other participants stressed that animal welfare should play a very important role in decision making; further, it was stressed that very similar principles and approaches should be used for both compliance checks and evaluation of testing proposals. Nevertheless, it was agreed that, in general, long-term testing for the aquatic environment should be considered as a standard information requirement (column 1) with possibilities for adaptation (column 2). With regard to the need to address 'triggers' for testing (e.g. PNEC refinement, high RCR, etc.), further discussion is needed to align on the different views.

Test proposed by the registrant	Sensitivity fish – *Daphnia*		
	Fish ≈ *Daphnia* (<10 times)	Fish 10 times more sensitive	*Daphnia* 10 times more sensitive
Fish	to be further discussed	Accept fish	Accept / Reject fish Request *Daphnia* ITS (if fish accepted)
Daphnia	Accept *Daphnia* fish? ITS	Accept *Daphnia* Request fish ITS	Accept *Daphnia*
Fish and *Daphnia*	Accept / Reject fish Accept *Daphnia* ITS (if fish accepted)	Accept fish Accept *Daphnia* ITS	Accept / Reject fish Accept *Daphnia* ITS (if fish accepted)

No alignment could be reached during the workshop for the entries highlighted in the table.

Testing strategy for the terrestrial environment

The strategy for terrestrial testing in relation to testing proposals and the guidance documents (Table R.7…) was discussed. Some participants were of the opinion that in general acute testing is not very informative for the terrestrial environment. A request for the test on micro-organisms for all four soil hazard categories has been discussed. Some uncertainty remained concerning the need to include micro-organisms for substances in hazard class 3. Most participants concluded that both the OECD 208 study and ISO 22030 should be acceptable for covering the long-term terrestrial toxicity to plants and both can be used to reduce the assessment factor.

Simulation testing in a PBT context

The issue was touched briefly. Some participants argued that a thorough justification of testing proposals is necessary as simulation testing should be based on the chemical safety assessment. It was concluded that further discussion is needed since decisions on degradation testing will most likely be very case-specific.

Following the reports from the break-out groups, it was further discussed in the plenary that there is a need to further align the strategy and standard texts for decisions for human health and environmental testing.

2.2 The future compliance check strategy

During the morning session of the first day, ECHA presented its ideas on the future strategy on compliance checks (CCH) which aims to support REACH's long term strategic objective through increasing the future quality of registration dossiers as much as possible.

The new strategy builds on the general principles of selection of dossiers as previously agreed by relevant stakeholders. The proposal is generated based on experiences and bottlenecks encountered during the previous years at the operational evaluation level within ECHA.

The following main lines were proposed:

- In the coming two years, ECHA would devote a proportion of CCHs on **areas of concern (AoC)** in the dossiers. These **"targeted CCHs"** will address selected (groups of) endpoints at the technical dossier level that are highly relevant for the safe use of substances. Dossiers would be selected for CCH using (mainly) IT-filtering of the IUCLID database that reveal clear non-compliances for the targeted endpoints. The group of "targeted CCHs" would also address those dossiers selected based on Art 41.5 of REACH (substances included in CoRAP, opt-outs of joint submissions) and dossiers flagged with high priority for CCH under the testing proposal examination. Overall, they could constitute around 60% of the compliance checks in the coming two years.
- The "**complete**" **compliance checks** would represent initially a smaller fraction of all CCHs, but gradually increasing when the overall database quality has increased through dossier updates. An important part of these "complete" CCHs would be randomly selected to generate a picture of the average dossier quality. "Complete CCHs" would require more quality time as they lead to exploring and establishing new scientific and legal policies for dossier evaluation decisions. "Complete CCHs" would constitute around 30% of all CCHs in the coming two years.
- In addition, a set of **CCHs on dossiers of general concern** would be carried out. This would target virtually empty dossiers (e.g. containing simple waiving statements for most of the endpoints or omitting the required chemical safety report). These obviously incompliant dossiers would be addressed by generic DDs and may cover up to 10% of all CCHs.
- While initial focus of the targeted CCH would be on the technical dossier content, over time CCH attention will shift more towards chemical safety assessment (CSA)/chemical safety report (CSR). This phasing of the CCH focus would allow improving of the basic information requirements in the first instance. Any major incompliance in intrinsic properties of substance needs to be tackled first before the CSA can effectively be addressed. In addition, ECHA can build up its capacity in the area of CSA and could strongly recommend registrants to provide future CSA/CSR updates with the use of the CHESAR tool.
- AoCs are helping to feed substances into the Authorisation or Substance Evaluation process. By addressing those AoCs that deal with for example PBT or CMR related characteristics, it could help to further identify future SVHCs. Similarly, AoC targeted CCHs could help to identify future candidate CoRAP substances.

This balanced CCH strategy would be the key to achieving (and potentially exceeding) the regulatory CCH target of 5% of the registration dossiers. Communication to all relevant stakeholders (registrants, the European Commission, Member State Competent Authorities) through different channels is regarded essential in order to ensure successful implementation of the proposed strategy.

Break-out groups

The new approach presented by ECHA was further discussed during the break-out groups with the aim of commenting upon the proposed future CCH strategy and providing feedback on its future implementation and communication. Another topic addressed was the areas of concern and the timing of the specific endpoints that would be targeted.

Break-out group 4 was specifically dealing with the general aspects while break-out groups 1 and 2 addressed the areas of concern in relation to human health and

environmental testing. The following generic conclusions could be drawn from the break-out group feedback reports:

a) General aspects of the future strategy

- The proposed strategy received very positive feedback and strong support from participants to move forward along this line. The advantages of the strategy have been addressed and underlined while it was stressed that potential pitfalls may be overcome through good communication. Furthermore, this strategy will ensure that most registered substances in the ECHA database would be checked for an area of concern, since most often the lead dossier is addressed.
- The key element in the success of the proposed strategy is communication with the relevant stakeholders: MSCAs, the MSC, registrants, etc. With MSCAs/MSC, close collaboration and cooperation along the process (e.g. its design, and area of concern identification) is envisaged. With regard to registrants, pre-warning campaigns were suggested which should focus on the educational aspect, e.g. providing concrete positive examples on acceptable approaches. Generic campaigns are preferred instead of addressing each individual registrant especially due to the time constraints (tight time schedule for developing the strategy). Other stakeholders should also be considered in this context i.a. NGOs.

b) Identification and development of areas of concern including their timing

- There was general agreement to start with simple AoCs, i.e. first address the clear non-compliance in the technical dossier, and gain experience with the overall approach. The AoCs can be further refined along the road, based on the experience gained.
- Identifying the right sequence of addressing the targeting is crucial, i.e. address some inter-related issues, for example water solubility in connection to aquatic toxicity.
- There should be a mix of phys-chem, environmental and human health endpoints.
- A member state emphasised the need to include exposure characteristics in the future. This was acknowledged but the limitations of developing AoCs that address exposure characteristics in technical dossiers were highlighted. Many exposure elements can be found in CSRs and it was explained that screening pdf-attachments with IT tools is very difficult at present.
- Additional criteria may be needed to narrow down the number of selected dossiers; other criteria to consider may be exposure considerations, C&L, etc.
- Member States expressed their willingness to contribute to further development of the AoCs. It was agreed to proceed as follows:
    - Organise webinars to present the first areas of concern and how the dossiers are selected in more detail
    - Written commenting on the first proposals
    - Further discussion on how to narrow down the scope
    - Regular meetings to keep the dialogue ongoing

c) Efficiency issues

- For efficiency reasons during the decision making process, proposals for amendments or comments should only be made for the targeted AoC related issues and preferably not on other elements of the dossier that were not considered during the targeted CCH.

- If there is a general agreement on the basic principles of the AoC approach and the targeting sequence is correctly implemented, it is assumed that no proposals for amendments are submitted. The feedback provided by the MSCAs on other non-compliances observed in the dossier can be given either through direct contact with ECHA or by providing comments. These comments would be stored in the Odyssey database and they would be used in future development of AoCs or for future rounds of targeted or full CCHs.
- Texts of the pilot (or template) draft decisions will be circulated for informal agreement.
- Further AoC driven CCH cases would be addressed by re-applying the agreed 'standard' draft decision texts.
- Further discussion and information sharing on efficiency issues is needed within CARACAL, and in order to achieve a gentlemen's agreement through MSCAs-MSC members.

d) Interlinks with substance evaluation

- Targeted CCH will be initiated for 2014 CoRAP substances for the concern linked to the CoRAP inclusion
- 2013 CoRAP substances –due to time constraints, only the substance identity issues will be addressed
- It should be considered to align the criteria for selection of dossiers for both processes, i.e. compliance checks and substance evaluation.

Plenary discussions

The discussion continued in the plenary session. The following issues were addressed:

- Some Member States indicated that there is a need to further discuss the proposed strategy with their colleagues before fully endorsing the approach.
- Although exposure, due to its inherent complexity, cannot be considered as an area of concern to start with (due to its inherent complexity), it was emphasised that it would be considered as an element to narrow down the number of identified dossiers that fall in the scope of other areas of concern. Once more experience has been gained with the overall approach, exposure could be considered an area of concern in its own right. It was proposed to first start with a set of more "simple" AoCs before embarking on exposure based filtering.
- The strategy needs to be further communicated to MSCAs, e.g. through CARACAL or if needed to the ECHA Management Board in order to get more general support.
- ECHA expressed the view that the new strategy will work only if a gentlemen's agreement is reached with the MSCAs on the decision making process. It has been stressed that for the CCH targeted on AoCs, the decision making process should focus on those areas and not on the whole dossiers, Member States may submit comments on other issues, e.g. exposure; the comments would be captured by ECHA for future use, and could be addressed through another ('complete') CCH if need be.
- Several Member States expressed their interest in contributing to the development of the strategy, and the areas of concern.
- The Commission expressed their support for the proposed strategy. They mentioned that this approach may eventually allow going beyond the target of 5 % for compliance checks.
- During the discussions, it was underlined that there is a need to communicate this approach to industry and explain in detail that the approach anticipates and

relies on a proactive role of registrants in updating their dossiers before receiving a draft decision or at least to “wake up” when a first draft decision on a single AoC is received.

2.3 Conclusions and follow-up

Conclusions and follow-up actions have been grouped as follows:

- general lines on improving efficiency
- sequential testing strategy
- future compliance check strategy

1. Improving the efficiency of dossier evaluation:

Reduce administrative burden

- Solve technical issues such as downloading the IUCLID files and bulk download on CIRCABC, provide remote access to REACH-IT for MSCAs.
- ECHA will provide MSCAs with an aggregated form of the draft decisions for faster screening, selection and prioritisation of DDs; the list should preferably contain administrative details such as type, UUID, registration number, country but also technical aspects such as endpoints/issues, country, tonnage band, C&L, CAS number, test guideline.

Improve interaction between MSCAs, the MSC, ECHA (Evaluation & MSC–S)

- Within ECHA, a single point of contact with evaluation should be established
- Within the MSCAs, a country coordinator could identify their expert for technical discussions
- Increase interaction between the MSCA representative responsible for dossier evaluation and the MSC member; the outcome of each MSC meeting needs to be properly communicated to the MSCA (and their supporting experts) and prior agreements made by the MSC should be considered before a proposal for amendments is submitted
- Establish expertise driven working groups on principle issues or to address thematic issues, and report back to the MSC meeting plenary group to agree a legal and scientific approach.
- In case the MSCA is unsure whether their concern warrants a proposal for amendment, they may first contact ECHA and then decide.

Proposals for amendments and comments

- Proposals for amendments should be formulated in a clear and concise form, taking into consideration previous agreements of MSC; the goal is that proposals for amendments are submitted in the form of text suggestions for changing different sections in the draft decision; this would also best ensure that the Registrant would understand the proposal correctly and could react to it.
- If a MSCA considers a particular endpoint/issue as a priority, they may submit proposals for amendments to trigger discussion and to achieve agreement on the endpoint/issue.
- For the compliance checks targeted to substance identity, no proposals for amendments should be submitted; ECHA will ensure that such cases (and other targeted compliance checks) are properly flagged in order to avoid possible misunderstandings.
- ECHA will no longer textually respond to the received comments in the RCOM. These comments will be captured in Odyssey (internal ECHA tool used in the evaluation workflow) for future use when the specific dossier is revisited again, and also an analysis will be made, if and when time allows, to determine if general trends can be established and acted upon.

- The MSCA's focus should be on proposals for amendments, however, an MSCA can also submit a **comment** indicating a need for discussion at an MSC meeting on an issue related to the cases subject to CA consultation. MSC-S will include the issue then on the Agenda of the MSC meeting.

Post-workshop note: At the time of drafting these proceedings, several actions have already been undertaken: the technical issues raised have been solved, Member States have used the possibility to contact ECHA during the commenting period and receive feedback regarding a dossier/decision; ECHA stopped addressing MSCA comments in the RCOM; expert groups/workshop like meetings associated with the MSC-meeting took place to prepare for the resolution of some issues. However, these measures have not yet lead to a decrease in the proportion of proposals for amendments received by ECHA and hence have not contributed to an increase in efficiency. Therefore, ECHA considers further measures which may need to be taken in the near future.

2. Sequential testing:

- For human health testing, a similar approach should be followed for both compliance checks and testing proposals i.e. the registrant should decide the order of the tests, ECHA should not assume this responsibility.
- Providing sufficient time for serial testing offers potential benefits for avoiding unnecessary animal testing; therefore parallel testing is to be avoided.
- Where appropriate, include a reminder in the draft decision about the potential for column 1 and 2 adaptations, as per the testing proposal.
- The environmental long-term aquatic endpoints should be considered as a standard information requirement (column 1) with possibilities for adaptation (column 2).
- For environmental testing further discussion is needed to align on the different views, with regard to the need to address 'triggers' for aquatic toxicity testing (e.g. PNEC refinement, high RCR, etc.), the strategy for terrestrial testing and simulation testing.
- There is a need to align the approaches and standard texts for decisions for human health and environmental testing.

3. Future CCH strategy:

- In general, there is agreement and support for the approach proposed by ECHA however, there is a need to further inform on and discuss the strategy before fully endorsing the approach (e.g. for information initially to CARACAL and if needed to the Management Board).
- Start with simple AoCs, e.g. clear incompliance in the technical dossier; further refinement of the criteria may be done gradually, based on the experience gained.
- Set-up collaboration with Member States willing to contribute to the further development of the approach.
- During the decision making stage on individual cases, proposals for amendments should only be focused on issues related to the targeted AoC. Any comments outside the AoC can be taken up by ECHA in the next rounds of CCHs.
- Further discussion is required for each area of concern in order to achieve gentlemen's agreements through MSCAs-MSC members.
- A communication plan towards registrants needs to be established.

Post-workshop note: At the time of drafting these proceedings, the development of areas of concern and cooperation with the Member States has been initiated.

3. SUBSTANCE EVALUATION

The workshop continued in the afternoon of the second day with the session on substance evaluation, ECHA presented the practical work associated with adoption of the first CoRAP and the start of the Substance Evaluation process under REACH. ECHA also presented future plans for updating the CoRAP. The core Substance Evaluation team at ECHA was also introduced.

3.1 Adoption of the first CoRAP and Roadmap for CoRAP update

3.1.1 Adoption of the first CoRAP

ECHA presented the timetable for adoption and publication of the first CoRAP, due on 29 February 2012. It was agreed to include contact details of the evaluating MSCA for each CoRAP substance in the published CoRAP. This will help to ensure transparency of the Substance Evaluation process. ECHA and the MSCAs recognised the need to manage the expectations of stakeholders about their participation in the Substance Evaluation process. ECHA proposed that a common approach on interaction with registrants and other stakeholders could be developed. MSCAs agreed with the proposal.

3.1.2 Roadmap for CoRAP update

Lessons learnt from the development of the first CoRAP were discussed. MSCAs and ECHA recognised the importance of an agreed, clear, simple, stepwise and structured approach to the selection of candidate CoRAP substances. MSCAs and ECHA should work together from the start of the process to avoid duplication of effort. The process for selection of candidate CoRAP substances should be integrated with other relevant REACH processes such as Authorisation and Restriction and also Classification and Labelling. ECHA plans to publish the Justification Documents for CoRAP substances from 2013 onwards to ensure transparency of the process. This would allow registrants and stakeholders to see why a particular substance was listed on the CoRAP. It could also avoid the misuse of the CoRAP as a 'black list'. MSCAs supported this proposal.

ECHA proposed a roadmap for updating the CoRAP. MSCAs welcomed the more structured, streamlined approach and it was broadly agreed. The roadmap has three phases:

- Phase 1. Identification of CoRAP Candidate Substances;
- Phase 2. Preparation of a Preliminary Draft CoRAP and
- Phase 3. CoRAP finalisation.

Phase 1. Identification of CoRAP Candidate Substances;

Work on Phase 1 would begin on 15 February 2012 until 1 June 2012. It involves IT screening followed by manual screening of REACH registration dossiers to select substances of potential concern. MSCAs could help to revise algorithms for the IT-based screening and will conduct manual screening. The manual screening exercise should focus on the area of concern flagged by the IT screening. The value of inclusion of the substance on the CoRAP should be considered in the light of any other regulatory action on that particular substance, either planned or ongoing. ECHA estimated that a maximum of two days is required to manually screen each substance and around 500 substances should be screened manually. ECHA explained that the IT screening activities in ECHA are coordinated by a cross-Directorate group to ensure a consistent approach. Screening is also required for the selection of registration dossiers for compliance check and for the selection of potential PBT substances for Authorisation. ECHA pointed out that these processes have different timelines but still require a common scientific approach.

Phase 2. Preparation of a Preliminary Draft CoRAP

Phase 2 of the roadmap would last from 1 June to 1 September 2012. It involves the allocation of substances to the preliminary draft CoRAP. MSCAs could choose to evaluate substances for which they conducted manual screening. In addition, MSCAs can propose candidate CoRAP substances selected according to their national priorities in accordance with Article 45(5) of REACH. Article 45(5) notifications can be submitted to ECHA by a webform. ECHA proposed the development of a set of simple, objective criteria for allocating the remaining substances to MSCAs. ECHA invited MSCAs to submit written comments on the allocation criteria described in a background document to the workshop. The allocation criteria would be discussed further at the Workshop on Substance Evaluation planned from 4 to 5 June 2012.

Phase 3. CoRAP finalisation

Phase 3 would begin on 1 September 2012 and would end with adoption of the updated CoRAP by 28 February 2013. The draft updated CoRAP and the Justification Documents for inclusion of each substance on the CoRAP would be finalised and submitted to the MSCAs and MSC by the end of October 2012. The MSC would prepare their opinion on the CoRAP and ECHA would adopt the CoRAP by 28 February 2013. The updated CoRAP and associated Justification Documents would be published.

3.2 ECHA Support to MSCAs on Substance Evaluation in 2012

ECHA will establish contact persons for each substance in the CoRAP for year 2012 and MSCAs can also submit questions to the functional mailbox substance-evaluation@echa.europa.eu.

Revised templates are available on CIRCABC for Substance Evaluation Draft decisions, the Substance Evaluation report and CoRAP justification documents.

ECHA offered to conduct consistency screening of draft decisions prepared by MSCAs. In order to plan the work, MSCAs are requested to inform ECHA in August of the expected delivery date of their draft decision. Draft decisions should be submitted for consistency screening two months before the final deadline for Substance Evaluation to ensure sufficient time for ECHA to conduct the check.

ECHA announced that two procedures are being drafted as part of ECHA's Quality Management System which cover Substance Evaluation and establishment and updates of the Community Rolling Action Plan. The procedures will be published on ECHA's website. ECHA agreed to prepare a checklist for MSCAs as a support for conducting the Substance Evaluations and to provide it to the MSCAs for comments.

ECHA will provide aggregated IUCLID 5 datasets for the 2012 CoRAP substances that have multiple registrations. This will give easier access to information than reviewing each dossier separately. However, it is a snap shot in time, not taking into account later dossier updates. ECHA is exploring the possibility of using the CASPER tool to spot dossier updates and to alert the MSCAs.

The following training for MSCAs is planned in 2012:

- Procedural and legal information on drafting Substance Evaluation decisions.
- Training on IT tools: Basic IUCLID 5 training, IUCLID 5 aggregated datasets, IUCLID 5 CSR plug-in and REACH-IT training.

Planning Substance Evaluation for 2012

The issue of joint Substance Evaluations was discussed. ECHA confirmed that a single MSCA holds responsibility for evaluating a substance on the CoRAP, i.e. is the official contact point, signs the Service Contract, submits the draft decision and the Substance Evaluation report and is responsible for carrying out the tasks related to the decision-

making process. However, it was agreed that any co-evaluator MSCA will also be indicated on the published CoRAP.

MSCAs asked about peer review of the Substance Evaluation reports. ECHA clarified that there is no requirement for a mutually accepted report in REACH. Its purpose is to record the assessment conducted by the MSCA and to support the draft decision (if issued). However, MSCAs can organise themselves by making peer reviews. As an option for such interaction, ECHA mentioned the organisation of a newsgroup in CIRCABC. ECHA intends to publish the draft Substance Evaluation report when the draft decision is issued and the final Substance Evaluation report when the report is updated with new information or when the evaluation is finished without a decision. It is therefore important that the public version does not contain any confidential information.

ECHA provided answers to MSCA questions regarding setting up Service Contracts for Substance Evaluation. Detailed answers can be found in a background document to the Workshop, agenda point 19.

The interaction of compliance checks and Substance Evaluation was discussed and broadly agreed. ECHA will conduct targeted compliance checks on substance identity for 2013 CoRAP substances. There is insufficient time to address other data gaps. For 2014 CoRAP substances a more comprehensive compliance check can be considered for filling key data gaps necessary for Substance Evaluation as there is still sufficient time for the decision making process.

Publication of list of new and existing substances deemed to be on the CoRAP

In the interest of transparency, ECHA intends to publish a list of the pending NONS decisions for which a decision in accordance with Article 16(1) of Directive 67/548/EEC was made. These substances are deemed to be on the CoRAP. In addition, those pending existing substance evaluations will be published as these substances are also deemed to be on the CoRAP. Publication of the list will be carefully planned and accompanied by a press release and Q&A document.

3.3 Conclusions and follow-up

- A workshop on Substance Evaluation is planned for 4 to 5 June 2012 to discuss and enhance the collaboration between the ECHA secretariat and the Member States
    - during the evaluation phase until submission of the possible draft decision and/or a substance evaluation report to ECHA,
    - during the decision-making process
    - for preparing the first CoRAP update and allocate substances among volunteering Member States.

  Accredited Stakeholders invited to MSC meetings as observers will be invited to the workshop.
- A common approach on interaction of registrants and other stakeholders with MSCAs on substance evaluation issues will be developed by volunteering MSCAs and ECHA. The approach will be discussed at the Workshop on substance evaluation in June 2012.
- The roadmap for updating the CoRAP proposed by ECHA was supported.
- ECHA will publish justification documents for CoRAP substances starting in 2013 to increase transparency of the process.
- The role of compliance checks on CoRAP substances to identify only significant data gaps which hinder the Substance Evaluation was broadly agreed.

ANNEX 1 - AGENDA

Workshop on Dossier and Substance Evaluation

31 JANUARY-1 FEBRUARY 2012

ECHA CONFERENCE CENTRE, ANNANKATU 18, HELSINKI, FINLAND

DRAFT AGENDA

TUESDAY 31 JANUARY 2012 **MORNING SESSION**		
8:30	**REGISTRATION**	
SETTING THE STAGE CHAIR LEENA YLÄ-MONONEN, DIRECTOR OF EVALUATION		
8:45	1. Welcome	Geert DANCET, Executive Director, ECHA
9:00	2. Introduction	Leena YLÄ-MONONEN Director of Evaluation, ECHA
SESSION ON DOSSIER EVALUATION		
9:15	3. Echa Framework and Principles on Dossier Evaluation	Leena YLÄ-MONONEN Director of Evaluation, ECHA
9:30	4. Future Compliance Check Strategy in Support of Strategic Long Term Objectives of REACH	ECHA presenter
9:45	5. Use of In-House IT Tools for Developing Algorithms for Prioritisation	ECHA presenter
10:00	6. Discussion	
10:20	Coffee	
10:35	7. Current Experience with Dossier Evaluation	ECHA presenter
10:50	8. Improvement of Efficiency in Dossier Evaluation	ECHA presenter
11:05	9. Dossier Evaluation – Overview of Some Developments in Decision Making	ECHA presenter
11:20	10. Member States' perspective on Dossier Evaluation	UK DE DK
12:05	11. Discussion	
12:15	Lunch	

AFTERNOON SESSION		
13:15	11. Discussion (continued)	
14:15	12. Overview on Drafting Evaluation Decisions – Basic Principles	ECHA presenter
15: 15	Coffee	
15:35	13. Break out groups Group 1: Targeted Compliance Checks: Higher Tier Human Health Endpoints and Issues of Sequential Testing Group 2: Sequential Testing Strategy: Higher Tier Environmental Endpoints Group 3: Future compliance check strategy Group 4. How to deal with proposals for amendments and comments in order to improve dossier evaluation process	
18:00	End of day 1	
19:30	**DINNER**	

WEDNESDAY 1 FEBRUARY 2012		
MORNING SESSION		
09:00	14. Report back from the break-out groups	Rapporteurs from 4 break-out groups
10:15	**COFFEE**	
10:35	15. General discussion	
11:45	16. Main conclusions	
12:10	17. Wrap-up and next steps	
12:30	**LUNCH**	

SESSION ON SUBSTANCE EVALUATION **AFTERNOON SESSION**		
13:30	18. Adoption of the First Corap and Roadmap for Corap Update	ECHA presenter
14:00	19. Substance Evaluation: Planning, Training and Transfer of Funds	ECHA presenter
14:30	20. Discussion	
15:30	21. Conclusions	
16:00	End of the workshop	

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