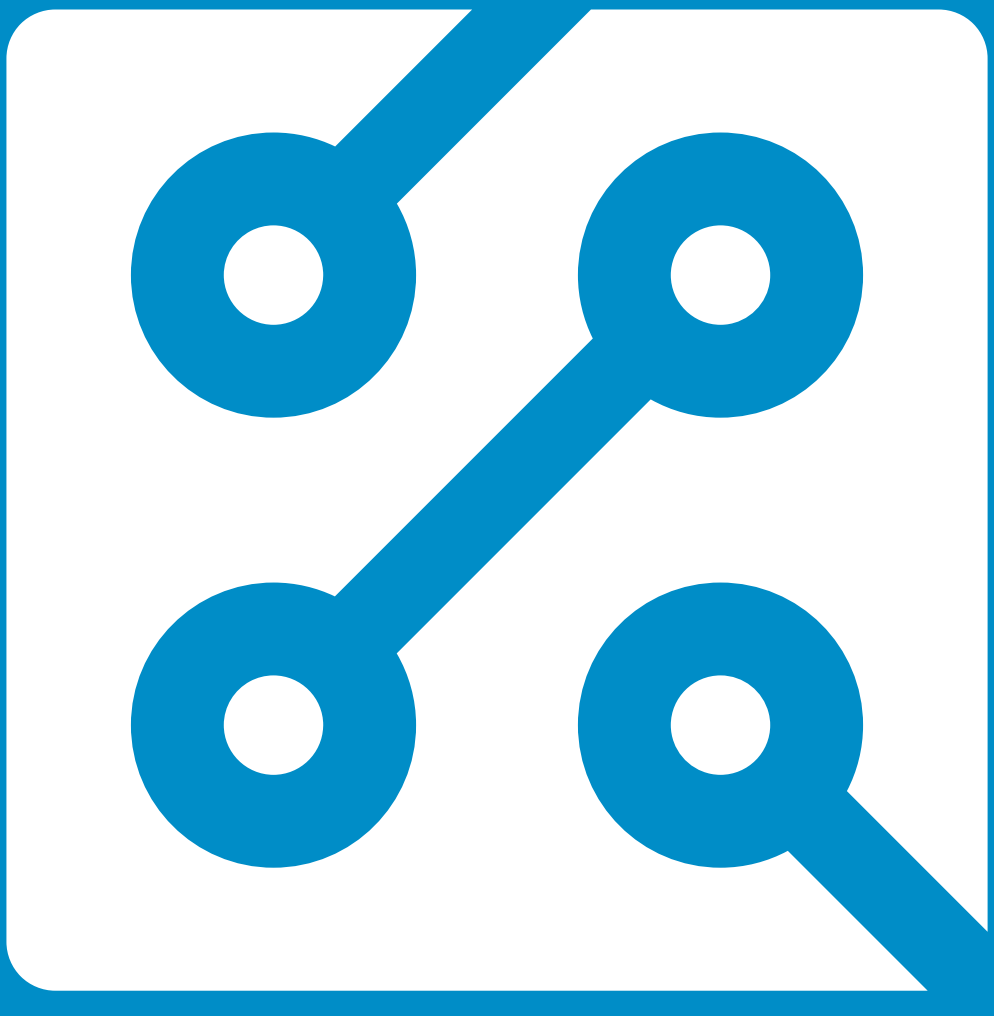
ECHA
EUROPEAN CHEMICALS AGENCY

Workshop on Implementing the Compliance Check Strategy

Proceedings

19-20 May 2015, Helsinki, Finland



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1. Summary

At the workshop, participants discussed the implementation of the new compliance check strategy for the period of 2015-2018 aiming to further refine and effectively implement the strategy and to enhance interaction with Member State competent authorities (MSCAs) in relation to compliance checks (CCH).

The participants included representatives from the Member States and EEA countries, the European Commission, Member State Committee accredited stakeholder observers and the ECHA Secretariat.

The workshop participants generally supported the proposed principles and did not raise major controversial issues. However, it is evident that the scoping of CCH in particular will still need practical experience and "confidence building" through real cases. It was also highlighted that the aim of CCH-scoping is to help to focus CCH on the main concerns and thereby ensure a more efficient, effective and impactful outcome. Interplay between (CoRAP) CCH and substance evaluation (SEV) was discussed and will be discussed further in the upcoming SEV workshop.

The newly improved integration of the selection of dossiers for CCH with the selection and manual screening of substances for other REACH and CLP processes (the common screening approach) was supported. The feedback from CCH, through its follow-up evaluation, to substance evaluation and risk management processes was also viewed as important.

Regarding the scoping of CCH, principles proposed on SID checks were generally supported. The relevance of substance identification profiles for both dossier evaluation and substance evaluation was acknowledged. General support was given to the CCH-scoping principles for hazard endpoints, with some reservations, and also to aligning the CoRAP CCH scope with these general principles. Member States emphasised the need for transparency on what has been checked under CoRAP CCH and what the outcome has been. Classification, PBT assessment and DNEL/PNEC derivation will be checked in almost all overall CCH but exposure assessment and risk characterisation will be evaluated for a subset of CCH cases.

ECHA plans to enhance the dissemination of information on the status and outcomes of dossier evaluation by the end of 2016, which was very much welcomed as a positive progress towards transparency. Concerning enhanced reporting and collaboration with MSCAs, ECHA presented elements for possible future developments. Based on the feedback from MSCAs, there is a clear need to continue optimising collaboration and reporting. MSCAs expressed a wish to minimise different information sources and instead have one place where the information would reside. The need for endpoint-specific structured information throughout the CCH process lifecycle was emphasised, as well as the need for more information on the status on cases that are of specific interest to a Member State.

Concerning "soft measure" campaigns and related complementary actions to improve dossier quality, the German study of REACH data availability was presented and discussed. In general, targeted letter campaigns were strongly supported and specific, horizontal campaigns targeting one endpoint/"scenario" throughout the ECHA registration database were preferred.

The announced ECHA pilot on targeted CCH verifying compliance with REACH Article 13(1) (which requires registrants to make sure that testing on vertebrate animals is done only as a last resort) was welcomed.

The workshop outcome was presented and follow-up actions on the implementation of the CCH strategy were agreed in the CARACAL meeting on 23-24 June 2015.

2. Introduction

From 19 to 20 May 2015, the European Chemicals Agency (ECHA) hosted a workshop on implementing the new compliance check (CCH) strategy to discuss the strategy for the period of 2015-2018. The aim of the discussions was to ensure further refinement and effective implementation of the strategy and to further enhance interaction with Member State competent authorities (MSCAs) in relation to CCH. The main topics discussed at the workshop were:

- selection of dossiers for CCH;
- scope of CCH (regarding both substance identification, SID, hazard endpoints and chemical safety reports, CSR elements);
- complementary measures to improve dossier quality;
- dissemination;
- reporting and collaboration with MSCAs; and
- use of CCH for verifying compliance with REACH Article 13(1).

The overall objective of the workshop was to seek alignment of views on these issues and in particular regarding the scope of CCH so that the number of proposals for amendments related to issues outside the scope of each CCH case as defined by ECHA would be minimised.

34 external participants from 21 EU/EEA Member States, the European Commission and from five Member State Committee accredited stakeholder observer organisations attended the workshop. In addition, 13 individuals mainly from the Member State competent authorities (MSCAs) listened to the open plenary sessions using WebEx. The accredited stakeholder observers of the MSC participated in the open plenary sessions and the related breakout groups of the workshop.

ECHA's Executive Director, Geert Dancet welcomed participants and thanked the MSCAs for their contributions for enhancing the compliance checks and other measures to improve dossier quality. He pointed out that ECHA has also started to measure the success of the compliance check strategy and report on it in the ECHA General Annual Report. The indicators already show good progress in improving the overall dossier quality due to measures taken already before the new strategy.

ECHA's Director of Evaluation, Leena Ylä-Mononen chaired the discussions. The main workshop topics were discussed in breakout groups. Most workshop participants contributed to two breakout groups. This report will only state the key conclusions reached in the workshop and will not record any individual contributions.

The workshop agenda is included in Annex I. Explanations of abbreviations used in this report can be found in Chapter 9.

3. Scope of compliance check

The scope and scoping of CCH was one of the main workshop topics. Three breakout groups discussed this based on ECHA's proposal for CCH-scoping regarding substance identification, SID, hazard endpoints and the elements of a chemical safety report.

3.1 SUBSTANCE IDENTIFICATION

A dedicated breakout group discussed substance identification as part of the CCH-scoping. Generic support with some reservations was given to the use of ECHA's margin of discretion not to systematically include an SID non-compliance in a CCH draft decision. It was highlighted that this approach is not about reducing the SID information requirements. It may rather contribute to focusing on those dossiers for which resolving an SID non-compliance matters most.

Possible cases for which the proposed approach would apply were discussed. It was indicated that inconsistencies within the substance identifiers is a non-compliance that needs to be resolved and therefore would normally be included in a CCH draft decision. It was however felt that, subject to a case-by-case analysis, a non-compliance such as missing analytical data or impurities might not always require inclusion in a CCH draft decision. For substances such as UVCBs or those subject to substance evaluation, the use of the margin of discretion regarding SID was perceived to be limited.

The role of the substance identification profile (SIP) in the application of the margin of discretion was also discussed. Briefly, the SIP sets the boundaries of the compositions registered collectively within a joint submission. It brings transparency regarding the compositions that were agreed to be addressed in the registration dataset. In the discussions, the relevance of the SIP in the application of the margin of discretion was acknowledged. It was generally recognised that transparency in the identity of the substance registered jointly may be instrumental in the use of the margin of discretion.

Under the new CCH strategy, the use of "soft" measures (e.g. letter campaigns) was considered complementary to improving the SID information in registration dossiers. These measures may minimise the risk of having CCH targeted on SID.

3.2 HAZARD ENDPOINTS

Concerning hazard endpoints, ECHA's proposal for scoping of the CCH can be summarised as follows:

INFORMATION	REVIEWED IN SCOPING	CHECKED FOR COMPLIANCE	REQUEST MISSING INFORMATION
Eight "super endpoints": Genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.	Always	Always	Always
Directly interrelated endpoints	Always	Conditional (if relevant for super endpoint/matters for substance safety)	If it matters
CLP (related to Eight super endpoints) and PBT assessment	Always	Always	If it matters
DNEL/PNEC	Always	Conditional (if classified and RCR > 0.1)	If it matters
Other endpoints	Always	Conditional (if triggered by scoping)	If it matters

These principles were generally supported. Member States felt that the CCH "scoping" process became clearer with the further clarifications and discussion in the workshop. These general scoping principles are the key issue for MSCAs to understand what is reviewed and what is checked by ECHA in a CCH. Concrete examples on applying the principles make them better understandable. Exposure information was highlighted as a key part in the dossier for the review and scoping step for CCH. So the evaluator also needs to look at the exposure assessment, e.g. if an exposure-based adaptation is used for any of the super endpoints or to decide if the exposure pathway/compartment is relevant or not. Therefore, exposure information is reviewed in almost all dossiers selected for CCH.

In the discussion, it was highlighted that the suggested threshold for DNEL/PNEC check of RCR 0.1 needs to be scrutinised based on the experience gained. The CCH-scoping approach also does not come without cost. For example, the test method for a 28-day repeated dose toxicity study is more advanced compared to a 90-day study design. So some effects may be seen in a 28-day study, which are not found in a 90-day study and cannot be seen if a proper 28-day study is not available. It was also pointed out that any equivalent concern in relation to SVHCs e.g. sensitisation comparable to the eight super endpoints should be reviewed in CCH and should be treated as any other super endpoint. Overall, if obvious and relevant non-compliance is noted, it needs to be checked and addressed if confirmed.

Skin sensitisation in the CCH scoping was addressed specifically, with the main concern often about worker safety. MSCAs indicated that there is a concern that the proposed alternative tests may not yet sufficiently cover this endpoint so they may not yet be accepted as alternatives. Therefore, ECHA should currently request the relevant animal test and not wait with CCHs until the alternative test methods are fully endorsed as these alternatives do not give all the information that would be needed for CLP purposes, among other issues. Skin sensitisation is also not currently parked under substance evaluation (SEV) but requested in an SEV decision, where relevant.

Regarding CoRAP CCH, MSCAs indicated that they generally agree with the proposed CCH scope alignment but concern was raised that the evaluating MSCA should be able to see all of ECHA's non-compliance findings in a similar manner as has been communicated so far. In addition, it would be very useful for the evaluating MSCA to be able to see which endpoints were checked and what was the outcome. Clear SID is also a key issue to be achieved under such a CCH.

Regarding CCH on SEV candidates, overall, it is necessary for CoRAP CCH to provide sufficient hazard data as the basis for the SEV to start. So key endpoints need to be covered in such a CoRAP CCH. The proposed CCH-scope approach seems therefore to be in general acceptable. Consultation of the evaluating MSCA on ECHA findings on non-compliances in the CoRAP CCH is a key here, seeking the views of the MSCA on what should be addressed under CCH and what should be left for SEV.

The MSCAs indicated that in some cases they are open to postponing SEV if some higher tier studies could be then requested under preceding CCH. If the substance is (planned to be) included in CoRAP due to national priorities, then the postponement may not be supported. The interface between CCH and SEV will continue to be discussed further in the upcoming SEV workshop (in November 2015).

3.3 REACH ANNEX I INFORMATION REQUIREMENTS (CSR)

CSR-focused CCH (CSR CCH) also addresses exposure assessment and risk characterisation, besides the hazard assessment that is covered in all overall CCH. The purpose and consequences of CSR CCH are to:

- Improve individual dossiers;
- Generate intelligence for other REACH and CLP processes;
- Inform about revisions to related guidance;
- Trigger a domino effect of improvements in other registration dossiers than those addressed in CCH for individual companies and sectors by sending clear messages about what is non-compliant;
- Impact on all dossiers in a joint submission;
- Impact on categories; and
- Spread the message that exposure is also under scrutiny.

The related breakout group proposed to use the following criteria and considerations for selecting dossiers for CSR-focused CCH (CSR CCH):

- Data gaps and wide-dispersive use;
- Substance needs to be classified;
- Ranking by hazard/potency was discussed;
- Selection can be based on combined hazard/exposure criteria;
- Both human health and environmental parts of the RCR calculation could be challenged;
- Investigate randomly selected dossiers to make sure that CCH possibility exists for all dossiers, i.e. to select CSR CCH cases also among the randomly selected CCH cases;
- Obvious deficiencies in risk management measures (RMMs);
- Triggers should also be in the exposure/RMM side; and
- Non-threshold effects, PBT, vPvB, RMM plausibility.

The following issues are recommended to be addressed in CSR CCH:

- CSR means all Annex I requirements;

- Tonnage: consistency between tonnages indicated in CSR and in IUCLID;
- Check that exposure scenarios are consistent throughout;
- Assessment of full life cycle of the substance;
- Credibility of effectiveness of RMMs – focus on correct RMMs and description of use;
- Correct selection of models;
- Correct use of models;
- PPE exposure modifiers;
- Challenge unrealistic exposure scenarios;
- Incomplete and inadequate information; and
- Lack of transparency.

In relation to these CSR CCH-scope issues, the threshold for adding the related request in a CCH draft decision was discussed. A range of views was expressed on whether the information should be requested even if no obvious concern could be seen arising from the non-compliance. DNELs and PNECs are applicable across all dossiers so non-compliances in their derivation should always be communicated. However, these are seen as part of the hazard assessment. It was also discussed which CSR information is necessary for MSCAs to consider RRMs and which information is necessary for communication in the supply chain. More generally, it was highlighted that the requests to improve CSR also have educational purposes, which can impact on other registration dossiers.

Overall, the MSCAs directed priority towards the eight super hazard endpoints. However, they recommended for ECHA to try to learn lessons from CSR CCH and apply them. ECHA should also use these lessons to formulate other appropriate actions, including better integration and planning of complementary measures, better guidance, webinars, MS actions and other communications with the balance between "carrot and stick".

Complementary measures are recommended to be followed up in compliance check otherwise they may be seen as a soft option. Non-responders are to be targeted for issues that matter. It was recommended that ECHA should enhance its capacity in terms of additional exposure expertise. In addition, it was considered that the number of dossiers assigned for a CSR-focused CCH could be increased among the total yearly number of dossiers selected for CCH. All in all, these dossiers selected for CSR CCH build a good starting point for the common screening.

The following follow-up issues were identified for CSR CCH:

- ECHA needs to create CSR CCH decisions that lead to predictable, enforceable outcomes.
- ECHA has found that dossier updates after CCH draft decisions sometimes present interesting and unpredictable outcomes for CSR issues that are not clear cut.
- It has been indicated that some national enforcement authorities (NEAs) struggle to enforce complicated regulatory scientific matters related to CSR when there is no clear and definite breach. These could be discussed in the Forum.
- It was pointed out that the available information on risk management measures feeds the common screening (ACROSS).
- CSR CCH is a journey and we are still exploring the issues we can address. However, CSR CCH must be seen in the context of other measures too.
- It is important to use all the relevant tools available to make a good CSR but also recognise that some companies may not have access to a full range of expertise and completing a proper CSR is a difficult job for them.

Overall, it was stressed that exposure information is important for risk assessment and needs to be

checked. There is a need to build an overall strategy to optimally address exposure issues in regulatory and complementary actions. CCH is a small but very important part of such activities. To increase the impact of actions planned and taken interaction between stakeholder groups engaged in CSR quality issues is very important. The relevant groups include the Exchange Network on Exposure Scenarios (ENES), the Nordic Exposure Group and the Exposure Expert Network under ACROSS. It was also recommended to develop further mechanisms to alert MSCAs about new CSR issues outside of the CCH PfA system.

We also need to continue further aligning with MSCAs on CCH CSR issues using these existing groups. Moreover, further research on the transparency of exposure estimation tools, their validation and better calibration is needs. The aim is to make fewer opportunities for error in their use. Feedback from implemented scenarios would also be beneficial.

4. Soft measure campaigns and related actions to improve dossier quality

Uta Herbst from the German Federal Institute for Risk Assessment (BfR) presented results from the German project on data availability in REACH registrations above 1 000 tonnes.

This is a good example of Member States national complementary actions that contribute to improving registration dossier quality. The project results were discussed, including whether the results should be communicated to individual registrants, as they might be interested in knowing the endpoints in their dossiers that have been evaluated and appear to not meet the information requirements, and whether the results should be utilised under common screening.

Communicating the results could improve the quality of registration dossiers by promoting spontaneous updates. It was noted that in previous letter campaigns conducted by ECHA, tailored letters, with a clear explanation on what is expected from registrants and helpdesk support were provided to registrants. This has largely contributed to the success of the campaigns. However, this type of support would be difficult to organise on such a large project. One suggestion was to address only the cases clearly appearing not to meet the information requirements and leave the complex cases. Another suggestion was to restrict the letter campaign to specific scenarios e.g. by targeting horizontal issues with general poor compliance.

Overall, more in depth analysis of the project results was felt to be beneficial, especially for understanding the underlying reasons behind the difference between the BfR and ECHA analyses on how many dossiers appear not to meet the information requirements. Furthermore, there was general support for including the BfR project results into ECHA processes, for example, in the common screening as well as conducting a letter campaign. The results of the BfR study could perhaps be better interpreted by splitting substances into groups, e.g. organics, inorganics, and petroleum compounds.

ECHA's plans for soft measure campaigns and related actions to improve dossier quality were also presented. Issues highlighted in the related discussion were that ECHA guidance documents would always lack behind scientific development. Therefore, their updates should focus on developing sector-specific guidance, put emphasis on guidance for new registrants and give concise guidance for REACH Annexes VII and VIII. It was also recommended to update the guidance on eye/skin irritation, acute toxicity, mutagenicity and skin sensitisation (later). Instead of guidance updates and an Article 54 evaluation report, the MSC Manual of decisions could be better used as a living document to reflect recent changes/state of play.

General support was given to continuing ECHA's letter campaigns but CCH should remain the core tool. Coordination is needed with national authorities and helpdesks before launching letter campaigns. Follow-up of letter campaigns will help creating a level playing field but is resource demanding. Targeted or horizontal campaigns may be more efficient than campaigns that are more general. For example, ECHA could target one endpoint/scenario throughout the database rather than targeting many endpoints for a limited number of substances.

Strategy to coordinate communication activities between ECHA and the Member States on targeted endpoints or targeted sectors is needed e.g. the MSCAs and ECHA can share presentations/communication material on campaigns. The current frequency of letter campaigns was assessed as workable by industry but it also depends on the scope (broad or narrow). For broad campaigns, about one campaign per year is preferred. It was also recommended that authorities should use a "domino effect" and plan to apply complementary measures besides CCH to extend the impact. It was also suggested to include animal testing considerations in a letter campaign. Letter campaigns could also be used to create a system of periodic or systematic registration updates.

The new ECHA dissemination pages planned for the end of 2015 were supported as part of ECHA's work on increasing transparency on activities and information on chemicals. It was recommended that ECHA should consider user friendliness and possibilities to extract information for different purposes and consider the right balance between simplicity and completeness in the provided information. Some participants proposed that ECHA should also consider naming companies in relation to CCH (to increase transparency on compliant and non-compliant companies). ECHA indicated that it does not plan to publish the identity of the registrants subject to dossier evaluation, in neither compliance nor non-compliance cases.

General support was given for ECHA's sector-specific discussions aiming to improve dossier information. Focus should be on sectors of interest, for example, textiles, paints and lacquers, and spray products. Focus could also be on specific substances within a sector, such as brominated substances and fluorinated substances. Understanding substances with high exposure potential was also discussed, showing the difficulty in identifying new important sectors to target. Possible avenues to explore could be using the information from consumer projects carried out in Member States, monitoring data, product registers and MSCA coordination groups to provide input.

5. Making better use of ECHA's available dossier evaluation information for dissemination and improved interaction with MSCAs

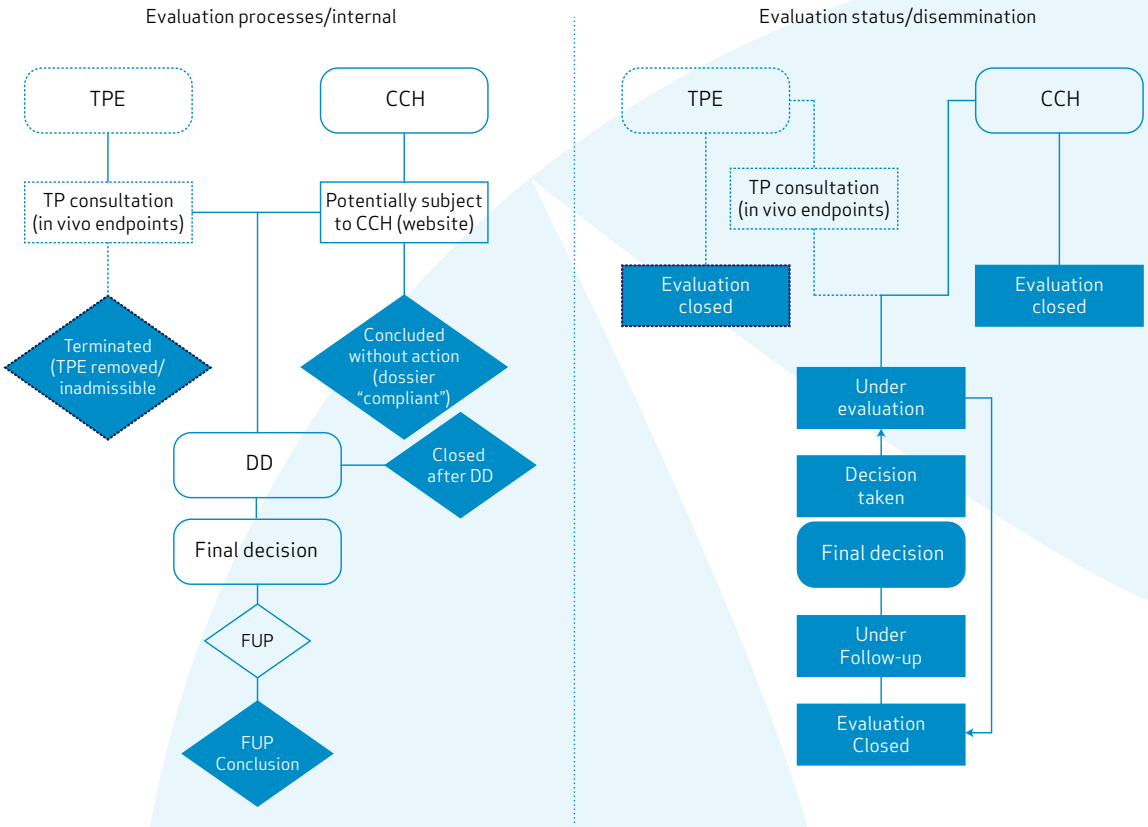
5.1 DISSEMINATION

ECHA presented its vision on how to publish further information related to the lifecycle of the dossier evaluation processes. This presentation aimed to make sure that stakeholders understand ECHA's vision and to gather their views as well as any other expectations and needs, in relation to the dissemination of dossier evaluation information.

ECHA's vision is to make more information available before the dossier evaluation decision is published (information related to the decision-making process) but also after its publication, in line with what was discussed in the previous CCH workshop in 2014. The vision aims to meet the commitment ECHA has made

towards increasing transparency of its activities. In addition, ECHA plans to disseminate more information, e.g. if a dossier is concluded and where the registrant does not receive a draft decision, if the registrant complied with the decision requirements after the indicated deadline. The figure below displays a schematic summary of this dissemination plan. By implementing this vision, ECHA will provide a complete and transparent view of the evaluation process life cycle.

Figure 1: Evaluation process life cycle



The following information is planned to be disseminated from dossier evaluation by the end of 2016:

- Status (within the CCH process lifecycle);
- Scope of evaluation (targeted, general, testing proposal);
- Outcome ((draft) decision, no action);
- Information requested in the decision;
- Deadline indicated in the decision;
- Links to the disseminated registration dossier and to the Appeal section (where applicable); and
- Date of closing the evaluation.

In addition, ECHA plans to start sending a copy of the Article 42(2) letter informing the MSCAs and the Commission about the conclusions of the dossier evaluation follow-up to the registrant in question.

The workshop participants generally supported ECHA's vision, especially concerning the status of evaluation. They indicated that while the dissemination of such information will be informative, it should always be linked to the scope of the evaluation undertaken, and to the reasons for closing an evaluation. Participants also stressed the need to include information on requirements contained in the decision. They also saw a

need to establish links between the outcome of evaluation and evaluation policies; therefore, the information published should be contextualised and linked (e.g. the decision to a related appeal, criteria for CCH selection).

The importance of clear instructions on the published new information at 'go live' was highlighted. Participants agreed with ECHA regarding a wider consultation, including the HelpNET, Industry and NGOs at a later stage of development and before the final implementation, to share and align on what ECHA wants to communicate.

Naming of registrants within the dissemination was discussed, together with its implications and different opinions were reflected. ECHA clarified that the focus of this information was on the substances and the related technical information.

It was felt that there is no need to display the outcome of common screening on ECHA's website, except in the context of the Public Activities Coordination Tool (PACT) and risk management option analysis (RMOA). Information on screening activities included in PACT and RMOA should be linked with the dossier evaluation information.

5.2 IMPROVED INTERACTION WITH THE MSCAS

Regarding the better use of evaluation information for reporting and collaborating with MSCAs, the MSCAs highlighted the need to optimise the collaboration and reporting. There is a need for structured information throughout the dossier evaluation process life cycle for all life cycle stages.

Improvements are needed in searching and tracking cases proposed for compliance check by Member States, including the priority and timeline for compliance checks. Better tracking and reporting of CoRAP cases as well as any other dossier evaluation cases of interest to the MSCAs is needed. The MSCAs recommended to minimise different information sources, preferably to one place where the information resides, with links to other sources and to contact point information. It was recommended to explore the use and expansion of the Portal Dashboard as the sole source of information, including use as a collaboration platform. There is a need to show different processes that a given substance is or has been under in one central location. The MSCAs also want non-REACH related processes to be included there.

The MSCAs pointed out the need for more predictable exchange of information about on-going dossier evaluations (e.g. for dossier evaluation decision referrals), which includes information on progress of dossiers in the follow-up stage. It was recommended to consolidate currently uploaded CIRCABC excel files to include "missing" information by using uniform identifiers and to integrate information from existing (or future) IT systems.

ECHA needs to strive for endpoint-specific reporting throughout the lifecycle from manual screening to follow-up in a historical perspective (from 2009). The need for a collaborative effort with the MSCAs was recognised to achieve this (i.e. by making sure that structured information is provided to and from ECHA). It was also felt that the common screening Master List is very useful but could preferably be provided in a more user-friendly platform. The planned use of the MSCA web-form for submitting proposals for amendments to dossier evaluation draft decisions offers benefits and structured information, even if internal MSCA processing may need a slight re-focus. ECHA needs to follow up with further communication activities with the Member States on the exact timelines for the introduction of the web-form. ECHA also took the action to explore how a word document could mimic and replace the web-form, offering a way to structure the information while still enabling easy collaboration in the drafting phase.

6. Use of compliance check for verifying compliance with REACH Article 13(1)

ECHA reported about the EU Ombudsman conclusion on a friendly solution on a complaint 1568/2012/AN concerning the scope of compliance checks with regard to verifying Article 13. This article concerns the obligation that information is to be generated whenever possible by means other than vertebrate tests and is one expression in the REACH Regulation of the principle that testing on animals should be as a last resort. To follow-up the friendly solution, ECHA is identifying cases with which to pilot the use of the compliance check process to examine the use of alternative methods by registrants to generate information on the hazards of substances. This may be one of the possible ways to allow the verification of compliance with REACH Article 13(1).

All in all, verification of non-compliance with Article 13(1) is a new task for ECHA and it was pointed out that Member States are ultimately responsible for enforcing possible non-compliances related to the "animal testing as a last resort" principle.

In the ensuing discussion, the participants' initial reactions were that the last resort principle should be preferably ensured prospectively though awareness raising and other measures and not retrospectively, for example, through compliance checks. There would, for example, be little value in asking for in vitro tests if, for example, an in vivo test has been submitted which ensures safe use of the substance. In addition, it was emphasised that endpoints where no alternative test methods exist should not be in the focus.

ECHA has used measures other than dossier evaluation decisions to address cases where registrants submitted a new test on vertebrate animals without awaiting ECHA's decision on a testing proposal. However, based on the feedback and because of other regulatory obligations, chasing such justifications has not been a priority for MSCAs.

Workshop participants recommended ECHA to emphasise its advice to registrants regarding the use of alternative approaches for those endpoints where in vitro-based testing strategies have been validated. It was also noted by one stakeholder that revisions to the REACH annexes will in the future encourage the greater use of alternative methods for some endpoints such as acute toxicity, skin/eye irritation/corrosion and skin sensitisation. This was particularly important given the 2018 REACH registration deadline.

7. Topical issues in dossier evaluation

ECHA informed about how it selects dossiers for compliance check and how Member States can propose cases for compliance checks. ECHA also used the opportunity to share information on topical issues in the dossier evaluation such as the new ECHA decision template, the implications of the REACH annex changes in relation to the extended one-generation reproduction toxicity study (EOGRTS) and the ongoing development of an Environmental Read-across Assessment Framework (Environmental RAAF). Regarding EOGRTS, it was indicated that there is a need for continued communication to industry. Registrants are also contacting national helpdesks on EOGRTS issues so they may need to be trained on this and other new information requirement developments. The new ECHA decision template affecting all new draft dossier evaluation decisions, as of September 2015, was welcomed. However, concerns were raised about moving the main part of the decision reasoning section in an annex.

8. Conclusions of the workshop and next steps

The following recommendations and conclusions were made at the workshop:

1. This overall aim of the workshop was met as the proposed principles were generally supported by the workshop participants. No major controversial issues were raised. However, it is evident that the scoping of CCH in particular will still need practical experience and "confidence building" through real cases. It was also highlighted that the aim of CCH-scoping is to help to focus CCH on the main concerns and thereby to ensure a more efficient, effective and impactful outcome.

2. The new screening approach for selecting dossiers for CCH that is integrated with selection and manual screening of substances for other REACH and CLP processes was supported. Lead and individual dossiers will be the main focus in CCH. However, member dossiers will be addressed in some CoRAP CCH and random CCH could also address them. The feedback from CCH, through its follow-up evaluation, to substance evaluation and risk management processes was also found important.

3. Regarding the scoping of CCH, the principles proposed on SID checks were generally supported, with some reservations regarding the margin of discretion ECHA applies in deciding whether to address less relevant SID deficiencies in the draft decisions. Reservations were indicated also for certain substances such as substance evaluation substances and UVCB substances with a high content of unknown constituents. The relevance of the substance identification profile (SIP, long used by industry) for both dossier evaluation and substance evaluation was acknowledged, as it would give the necessary overview on the identity of the substance jointly registered and on what test data is required for that substance.

4. General support was given to the proposed CCH-scoping principles concerning the hazard endpoints, again with some reservations. General support was also given to aligning the CoRAP CCH scope with these general principles. Member States emphasised the need for transparency on what has been checked under CoRAP CCH and what the outcome has been.

5. Interplay between (CoRAP) CCH and SEV was discussed and will need further discussion in the next substance evaluation workshop planned to take place on 19–20 November 2015. Some MSCAs expressed the view that in CCH of CoRAP substances, ECHA could also request standard information falling into the area of initial concern for substance evaluation. This is somewhat contrary to what had been agreed previously (i.e. CCH normally not touching the endpoints falling into the area of the initial substance evaluation concerns). The current policy is based on the fact that we should avoid interference between the two processes, especially if CCH requests for CoRAP substances do not allow getting such information available before the start of substance evaluation. Some MSCAs indicated that for this reason they are open to postponing substance evaluation if some higher-tier studies could be requested under preceding CCH. However, postponement should be an exception and decided on a case-by-case basis. Furthermore, ECHA clarified that should the CCH be used to generate information in the area of the identified concern, the evaluating Member State should afterwards reconsider if substance evaluation is still needed to clarify any concerns and if further information is still necessary. If not, the substance would have to be withdrawn from the CoRAP and, where appropriate, a risk management option analysis would be prepared. Regarding the scope, it is important that Member States in collaboration with ECHA recognise upfront, i.e. during the manual screening, if the substance needs to be included in the CoRAP because substance evaluation is the best tool to clarify the concern, and whether the substance should undergo a CCH first.

6. Apart from classification, PBT assessment and DNEL/PNEC derivation, ECHA's capacity to address exposure and CSR elements under CCH will be limited and hence exposure assessment and risk characterisation will be evaluated only for a selected number of CCHs per year. There was a general understanding on this approach, due to the available resources. The importance of reliable exposure information was emphasised, as it is one of the prioritisation criteria in the CCH strategy and will inform the CCH scoping.

   It was acknowledged that CCH is not the only measure to address CSR issues and authorities should use the "domino effect" more and plan to also apply complementary measures to extend the impact. As for the hazard, it was acknowledged that ECHA can use its discretion to decide what CSR non-compliances matter and need to be addressed. There is also a need for further alignment with Member States and the Forum on following up CSR issues under CCH.

7. The announced ECHA pilot on targeted CCH verifying compliance with REACH Article 13(1) (requiring registrants to ensure that testing on vertebrate animals is done only as a last resort) was welcomed. In the related discussion, the MSCAs indicated that they prefer prospective, general measures (communication, guidance, advice) and give a lower priority for using CCH for retrospective verification. This was generally supported by the workshop. It was noted that ECHA should seek to establish a regular communication with test laboratories to share information on non-animal testing strategies, as these organisations are often the ones advising the registrants on the choice of methods.

8. ECHA plans to enhance the dissemination of information on dossier evaluation status and outcomes by the end of 2016, which was very much welcomed as it was seen as a positive progress towards transparency. It was recommended to continue consulting stakeholders on the practical implementation aspects. In general, the need to inform registrants and the public at large about positive evaluation outcomes was also highlighted. ECHA does not plan to publish the identity of the registrants subject to dossier evaluation (in neither compliance/non-compliance cases); different opinions were expressed regarding this aspect. The need to contextualise the published dossier evaluation information was also highlighted. This can be done, for example, by indicating relevant policies and related processes (e.g. appeals), the scope of evaluation and the criteria for selection of the CCH case.

9. Concerning enhanced reporting and collaboration with the MSCAs, ECHA presented elements for possible future developments. Based on the feedback from the MSCAs, there is a clear need to continue optimising collaboration and reporting. In particular, several comments were received on the planned IT system changes (sCIRCA-BC versus use of REACH IT annotations and webforms and the Portal Dashboard). The MSCAs expressed a wish to minimise different information sources and have instead one place where the information would reside. The need for endpoint-specific structured information throughout the lifecycle of the CCH process was emphasised as well as the need for more information on the status of cases that are of specific interest to a Member State.

10. Concerning the "soft measure" campaigns and related complementary actions to improve dossier quality, representatives from the BfR presented the German study of REACH data availability. The workshop discussed how such outcomes could be used by different actors. All acknowledged that the German study provides valuable findings. However, it was not clear if the best route to communicate them is a generic letter campaign or whether instead only certain specific, reoccurring deficiencies should be followed up in letter campaigns. In any case, integration of the German study results into ECHA's common screening should be done. BfR and ECHA will further explore how the results can be used in the most effective way to select further substances for CCH and how this information can be communicated to registrants in a meaningful way. The final German project report was published

on the second workshop day, 20 May at http://www.umweltbundesamt.de/en/publikationen/reach-compliance-data-availability-of-reach. German representatives indicated that the detailed project results will also be made available to other MSCAs on request.

No other Member State than Germany indicated plans for soft measures complementary to CCH to address dossier quality issues. In general, targeted letter campaigns were strongly supported and horizontal campaigns (target one endpoint/"scenario" throughout the ECHA registration database) were preferred. The MSCAs emphasised the need for stronger and earlier interaction with CAs (including helpdesks) and pointed to possibilities to "replicate" or reinforce ECHA campaigns at a national level. However, a widely shared view was that such campaigns should not drain resources from CCH.

There was also strong support on ECHA's efforts to increase transparency by disseminating registration information, which also by itself contributes to improving the dossier quality. However, dissemination needs to strike a balance between simplicity and completeness. Obtaining more information on exposure potential of substances was seen as important and hence ECHA should further stimulate sector-specific discussions. All actors should utilise national (consumer) projects, product registers and monitoring information.

Concerning other complementary measures, it was recommended to shift the focus of REACH guidance updates to more streamlined and concise advice tailored for Annex VII and VIII registrants and for endpoints where science is evolving (e.g. skin/eye irritation, acute toxicity, skin sensitisation, mutagenicity). Such advice could also be sector-specific. A living "manual of decisions" was seen as a possible way to harvest and disseminate experience from past cases from substance evaluation and CCH in a more digestible way.

As a follow-up to the workshop, ECHA presented an oral report from this workshop to the MSC meeting of 8-11 June 2015. The workshop outcome was also presented at and follow-up actions on the implementation of the CCH strategy were agreed in the CARACAL meeting of 23-24 June 2015.

9. List of Abbreviations

ACROSS	A common road to substance screening
CA	Competent authority
CARACAL	(Meeting of) competent authorities for REACH and CLP
CCH	Compliance check
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CLH	Classification and labelling harmonisation
CLP	Classification, Labelling and Packaging (Regulation)
CoRAP	Community rolling action plan
CSR	Chemical safety report
DD	Draft decision
ECHA	European Chemicals Agency
ECHA-S	Secretariat of the European Chemicals Agency
ED	Endocrine disruptor
EOGRTS	Extended one-generation reproduction toxicity study
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
MSEA	Member State enforcement authority
NEA	National enforcement authority
PACT	Public Activities Coordination Tool
PfA	Proposal for amendment
PBT	Persistent, bioaccumulative, toxic
PNEC	Predicted no effect concentration
RCR	Risk characterisation ratio
RMM	Risk management measure
RMO	Risk management option
RMOA	Risk management option analysis
SEV	Substance evaluation
SID	Substance identification
SIP	Substance identification profile
SVHC	Substance of very high concern
TPE	Testing proposal examination

Annex I – Agenda

ECHA COMPLIANCE CHECK WORKSHOP 2015
IMPLEMENTING THE COMPLIANCE CHECK STRATEGY
19 – 20 MAY 2015
ECHA CONFERENCE CENTRE, ANNANKATU 18, HELSINKI, FINLAND

DRAFT AGENDA

TUESDAY 19 MAY 2015 MORNING SESSION MEETING ROOM MARIE SKLODOWSKA CURIE CHAIR: LEENA YLÄ-MONONEN, DIRECTOR OF EVALUATION		
8:30	Registration	
09:00	Welcome	Geert DANCET Executive Director, ECHA
1. INTRODUCTION BY ECHA		
09:10	1.A. Objectives of the workshop	Ofelia BERCARU Head of Unit Evaluation 3
09:20	1.B. Status of compliance check strategy implementation - Overview	Leena YLÄ-MONONEN Director of Evaluation, ECHA
	Q&A	
09:40	1.C Selection of dossiers for compliance check	Claudio CARLON Head of Unit Evaluation 2
	Discussion	
10:20	Coffee	
10:40	1.D. Scope of compliance check: eight super endpoints and what else?	Hannu BRAUNSCHWEILER Team Leader, Evaluation
	1.E. Compliance check of Annex I Information Requirements (CSR)	Jesus VAZQUEZ RODRIGUEZ Scientific officer, Evaluation
	1.F. Better use of dossier evaluation information for improved interactions with MSCAs and dissemination	Guilhem DE SEZE Head of Unit Evaluation 1
	Discussion	
2. SOFT MEASURE CAMPAIGNS AND RELATED ACTIONS TO IMPROVE DOSSIER QUALITY		
11:50	2.A. Results from the project of German Federal Institute for Risk Assessment (BfR) on data availability in REACH Registrations	Uta HERBST Federal Institute for Risk Assessment, Germany
12:20	2.B. ECHA plans for soft measure campaigns and related actions to improve dossier quality	Christel MUSSET Director of Registration
	Discussion	
13:00	Lunch	

AFTERNOON SESSION		
14:00	3. SCOPE OF COMPLIANCE CHECK - ASSESSING COMPLIANCE WITH ARTICLE 13(1)	George CARTLIDGE Team Leader, Evaluation
	Discussion	
14:30	5.A. Topical issues in the dossier evaluation from ECHA: New ECHA Decision template	Minna HEIKKILÄ Head of Unit Legal Affairs
4. BREAKOUT GROUPS		
14:45	Practical arrangements of breakout groups	Hannu BRAUNSCHWEILER Team Leader, Evaluation
	4.1 Making better use of ECHA's available dossier evaluation information for dissemination Meeting room: Marie Sklodowska Curie	Breakout group chair: Laurence HOFFSTADT Scientific officer, Evaluation
	4.2 Better use of Evaluation information for reporting and collaboration with MSCAs (CA session) Meeting room: K176	Breakout group chair: Guilhem DE SEZE Head of Unit Evaluation 1
	4.3 Measures complementary to compliance checks Meeting room: Marie Sklodowska Curie	Breakout group chair: Christel MUSSET Director of Registration
	4.4 Scope of compliance check: Substance Identity (CA session) Meeting room: K323	Breakout group chair: Ronan NICOLAS Scientific officer, Substance Identification and Data Sharing
	4.5 Scope of compliance check: Hazard endpoints (CA session) Meeting room: K324	Breakout group chair: Ofelia BERCARU Head of Unit Evaluation 3
	4.6 Scope of compliance check: CSR (CA session)	Breakout group chair: Claudio CARLON Head of Unit Evaluation 2
16:20	Coffee	
16:40	Change of breakout groups: Choose another preferred group (Note: CA session groups only for MSCAs and COM.)	
18:00	End of Day 1	
18:00 - 19:00	Cocktail reception	

WEDNESDAY 20 MAY 2015 MORNING SESSION MEETING ROOM MARIE SKLODOWSKA CURIE CHAIR: LEENA YLÄ-MONONEN, DIRECTOR OF EVALUATION		
	5. TOPICAL ISSUES IN THE DOSSIER EVALUATION FROM ECHA	
09:00	5.B. Update on implementing the EOGRTS Information Requirement	Ingo BICHLMAIER Scientific officer, Evaluation
	5.C . Brief introduction to the environmental Read-across Assessment Framework (Environmental RAAF)	Konstantinos PREVEDOUROS Team Leader, Evaluation
09:40	6 REPORT BACK FROM THE BREAKOUT GROUPS AND DISCUSSION	Rapporteurs from break-out groups
11:00	Coffee	
11:20	REPORTING BACK FROM THE BREAKOUT GROUPS AND DISCUSSION CONTINUES	
12:20	7. GENERAL DISCUSSION OF THE IMPLEMENTATION OF THE CCH STRATEGY	
12:50	8. CONCLUSIONS OF THE WORKSHOP	
13:15	Lunch	

AFTERNOON SESSION		
14:15	9. FURTHER DISCUSSION ON THE SCOPE OF CCH AND INFORMATION ON UPCOMING DEVELOPMENTS (CA SESSION))	
14:15	9.A. Optimisation of IT interactions with Member States	Damiano VESENTINI Scientific officer, Evaluation
14:30	9.B. Further details about implementation of the REACH Annex changes in relation to EOGRTS	Ingo BICHLMAIER Scientific officer, Evaluation
14:45	9.C. Further discussion on the scope of compliance check	
16:00	End of workshop	

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