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Workshop on Compliance Check 2014-2018 – contributing to high quality information for the safe manufacture and use of chemicals

Proceedings

Helsinki, 31 March –1 April 2014

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Executive summary

At the workshop, compliance check (CCH) and its strategic direction for the period of 2014-2018 was discussed. The participants included representatives from the Member States and EEA countries; Member State Committee members; two members of the ECHA Management Board Working Group on Planning and Reporting; Member State Committee accredited stakeholder observers representing industry; workers and public interest NGOs; the European Commission; and the ECHA Secretariat.

Compliance check was discussed in the context of ECHA's Multi-Annual Work Programme (MAWP) and of regulatory and non-regulatory activities foreseen to meet the ECHA strategic objective of maximising the availability of high-quality information. ECHA presented the progress and experience with CCH from 2009 to 2013 and indicated elements of the current CCH strategy, which could be updated.

Instead of addressing compliance check in isolation, ECHA should – in line with its strategic objectives set in the Multi-Annual Work Programme 2014 – 2018 - address compliance in an integrated manner, i.e. together with other measures for improving dossier quality and also in view of how these measures could better support authorities to identify, select and prioritise right substances for action. This approach builds on two major learnings: 1) CCH is an important but neither the only nor always the most cost-efficient measure to improve dossier quality and 2) stronger links and synergies should be built between CCH and other measures aiming to improve dossier quality and other REACH and CLP processes to ensure overall effectiveness and efficiencies. These learnings are important also in view of the declining resources of ECHA and other authorities.

Maximising the availability of high-quality data and creating incentives for better quality dossiers was one of the horizontal themes discussed in the workshop. There was consensus on the need to improve registration dossier quality due to the widespread non-compliance of dossiers, and therefore action by all parties is needed. ECHA is not the only actor to improve dossier quality and address chemicals of concern. On the contrary, many actions would be insufficient without support from other actors. There is a need to activate all related actors: Member States authorities, industry associations and individual companies, public interest organisations and the Commission. One of the strategic aims is to mobilise authorities to use REACH registration data intelligently to identify and address chemicals of concern. This requires compliance checks to be more closely linked to other REACH and CLP processes, but this should also work both ways. The efficiency and effectiveness of all related actions was frequently highlighted.

The workshop found a general agreement that the revised CCH strategy should concentrate on the right substances of concern, those relevant for safe use – both in the selection of substances for compliance checks and for other measures. However, besides CCH, other actions are needed to improve dossier quality. There is a need to mobilise all actors to begin such complementary measures. Another principle of the updated strategy should be the effective and efficient use of different types of CCH and the use of different CCH types fitted for purpose. Before launching CCH, other, lighter and less costly measures should first be applied, where relevant, but reserving always the possibility to use CCH if other measures prove not to bring the wanted results. Furthermore, enhancing interaction with the Member States must be continued to improve efficiency of the CCH process, including its follow-up phase and reporting.

Based on the Workshop conclusions, ECHA will present the key elements for an updated strategy for discussion in the July 2014 CARACAL meeting and will inform the ECHA Management Board meeting accordingly in September.

1. Introduction

From 31 March to 1 April 2014, the European Chemicals Agency (ECHA) hosted a workshop with the title "Compliance check for 2014-2018 – contributing to high-quality information for the safe manufacture and use of chemicals".

The scope of the workshop was the compliance check (CCH) and its strategic direction for the period of 2014-2018. The issue was addressed in the broader context of ECHA's MAWP 2014-2018 and, in particular, the suite of regulatory and non-regulatory activities foreseen to meet ECHA strategic objective 1 – maximising the availability of high-quality information to enable the safe manufacture and use of chemicals. The focus was on when and for which data quality deficiencies it would be most effective to begin the CCH process, taking into account the possibilities and limitations based on the experiences of ECHA and the Member States. The workshop also addressed the potential role of CCH in making sure that the relevant substances (of concern) are identified in the most effective manner. Therefore, the interlinks between CCH and testing proposal examinations, substance evaluation, regulatory risk management measures and the other activities of ECHA and the Member States relevant for the quality of REACH dossiers were also discussed.

The main objectives of the workshop were:

1) To reach a common understanding on:

- The regulatory and non-regulatory activities being undertaken to make sure that the information in REACH dossiers is of high quality,
- The role that CCH can play in improving data quality in general (including chemical safety reports - CSRs) and in particular for which situations the initiation of the CCH process would be the most effective way to tackle the deficiencies foreseen in the REACH dossiers, and how to optimise the impact of CCH decisions by complementary actions,
- Interplay of CCH with substance evaluation and risk management processes under REACH and CLP,
- The general principles and priorities for selecting substances and dossiers for CCH in 2014-2018.

2) To identify and agree on the areas that need specific involvement or responsibilities of Member State authorities to ensure maximum impact of the CCH on chemicals management under REACH.

3) To collect input on how to continue improving the interaction between ECHA and the Member States, including their involvement through (preparatory) expert input (lessons learnt from the Areas of Concern (AoC) approach).

4) To collect input on how to continue improving the efficiency of the CCH and the related decision-making process.

5) To collect input on how to improve reporting on and communication of the results of the CCH.

The desired outcomes of the meeting were:

- A common understanding of the role that CCH can play in increasing the overall quality of REACH registration dossiers,
- Agreement on the general principles, priorities and other key elements of the CCH strategy for 2014-2018,
- Agreed recommendations related to the issues listed above, including proposals for any necessary follow-up work.

The workshop was attended by 56 participants. These included representatives from 19 Member States and EEA countries; members of the Member State Committee (MSC); members of the ECHA Management Board Working Group on Planning and Reporting; MSC accredited stakeholder observers representing industry; workers and public interest NGOs (Cefic, ClientEarth, CONCAWE, European Coalition to End Animal Experiments, EUROMETAUX, European Environmental Bureau and European Trade Union Confederation); the European Commission (DG Enterprise and Industry and DG Environment). The accredited stakeholder observers of the MSC were participating in the open plenary sessions and the related breakout sessions of the workshop.

Delegates from a Member State authority announced that any statements they made during the workshop were the professional opinion of the delegates and not the opinion of their respective MSCAs.

The workshop agenda is included in Annex I with the workshop divided into six sessions.

After ECHA's Deputy Executive Director welcomed the participants, the objectives were introduced by ECHA. The outcomes and lessons from CCH in 2009-2013, CCH in the context of the ECHA Multi-Annual Work Programme 2014-2018 and ECHA strategic objectives 1 and 2 were also introduced. Feedback and observations from outside ECHA were given by competent authorities, the Commission and stakeholder observers on the implementation of CCH together with views on complementary actions to improve dossier quality.

In the afternoon of the first day, four breakout groups were formed to continue the morning plenary discussions. The breakout group discussion topics and their background were presented in the plenary at a general level so that all workshop participants had a proper background also for second day's plenary discussions. The four breakout group topics were the following:

- Breakout group A: Prioritisation and selection of substances for action with the aim to improve their dossier quality (open group)
- Breakout group B: Complementary measures to improve dossier quality (open group)
- Breakout group C: Optimisation of CCH to improve dossier quality (competent authority session)
- Breakout group D: Enhanced interaction with MS to improve the efficiency of the CCH process (competent authority session)

In the morning of the second day, the rapporteurs presented the findings of each breakout group to the plenary session. The reports were followed by a plenary discussion. After the plenary discussions on the issues presented, the workshop was concluded and ECHA's Director for Evaluation made final remarks.

Explanations of abbreviations used in this report can be found in Chapter 6.

2. Introduction to compliance check and its context, and feedback on the implementation of compliance check

2.1 INTRODUCTION TO COMPLIANCE CHECK AND ITS CONTEXT

Jack de Bruijn, ECHA's Director of Risk Management, presented compliance check in the context of the ECHA Multi-Annual Work Programme 2014-2018 and ECHA's strategic objectives. ECHA's four strategic objectives are:

1) Maximise the availability of high-quality data to enable the safe manufacture and use of chemicals.

2) Mobilise authorities to use data intelligently to identify and address chemicals of concern.

3) Address scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors.

4) Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.

He highlighted the role of CCH in the implementation of REACH and its links to ECHA's Multi-Annual strategic objectives as well as its interaction with other REACH (and CLP) processes. CCH is not an aim as such but should be seen in relation to ECHA's strategic objectives 1 and 2. CCH is part of the overall strategy to improve dossier quality, so it is one important component among other tools and approaches. CCH must be used together with other actions, which, depending on the problem, can be more effective than the CCH. The other REACH and CLP processes (CoRAP, Classification and Labelling harmonisation - CLH, Candidate/ Authorisation List and Restriction, including the SVHC Roadmap activities) are 'customers' of CCH. This needs to be taken into account in the selection of substances, in the use of CCH results and in the CCH follow-up phase.

Jack de Bruijn indicated that the Multi-Annual Strategy should be built on the following "blocks". REACH is designed to ensure the safe use of chemicals. A key role of industry under REACH is to collect information needed to demonstrate the safe use of substances and to provide information on adequate safety measures in the supply chain. ECHA, in its role of implementing REACH, must efficiently use all possible legal measures as well as other (complementary) approaches to guarantee that industry adequately exerts its duties in ensuring the safe use of chemicals. A key role for ECHA and the Member States under REACH is to focus on substances that deserve EU-wide regulatory risk management measures. A pre-requisite for the above is that information collected by industry is of "high quality" so that the overall system works. Other enabling factors to ensure such impact are that ECHA and the Member States have the necessary expertise and work efficiently (regarding process, IT and use of resources).

Jack de Bruijn stressed that dossier quality is essential as it proves that chemical companies have assumed their responsibilities as required by REACH. Reliable data are also needed to make a responsible risk assessment and to recommend adequate safety measures. Registration information is the basis for authorities to judge whether risks are adequately controlled or if there is a need for further regulatory actions. Good dossier quality also creates public confidence.

Leena Ylä-Mononen, ECHA's Director of Evaluation, reported on the main outcomes and lessons from compliance check in 2009-2013. A written report on the main outcomes and lessons learnt by ECHA had been distributed to the workshop participants beforehand.

For 2009-2013, the main conclusion has been that compliance check works well overall. The quantity of output and coverage of high production volume substances and the scientific and legal quality of CCH outcomes and their desired impact on individual registrants have been at the desired level or, in some cases, even exceeded. However, CCH will alone not be sufficient because what we now know about the overall dossier quality status is calling for further action.

This is especially because the 5% CCH target for the registration dossiers remains a small proportion of all dossiers and, so far, the so-called multiplier effect of CCH decisions has been limited.

Leena Ylä-Mononen indicated that despite the big efficiency improvements made, CCH is resource intensive, in particular the overall CCH and especially where ECHA's draft decision receives proposals for amendment from the Member States. Resources assigned to CCH are also likely to decrease and will become more and more "pre-booked", for example, for specific campaigns for substance evaluation related substances or for follow-up actions on previous CCH.

ECHA has also observed that CCH is not optimally synchronised with other REACH processes (e.g. restriction, authorisation and CLH) so that the most relevant substances for regulatory risk management and safe use are not always selected for CCH. In addition, the results of CCH and new information received are not seamlessly fed into other REACH and CLP processes.

In the plenary, the drivers for making industry submit good-quality registration dossiers and incentives to stop poor-quality dossiers were discussed. It was indicated that Article 5 of the REACH Regulation ("no data, no market") is a key basis for these actions. Many Member States are building their enforcement action on this article and it was indicated that they could do more here.

2.2 FEEDBACK AND OBSERVATIONS FROM OUTSIDE ECHA ON THE IMPLEMENTATION OF CCH AND VIEWS ON COMPLEMENTARY ACTIONS TO IMPROVE DOSSIER QUALITY

Magnus Løfstedt from the Danish competent authority shared their views on whether activities complementary to CCH can be used to improve the poor quality of REACH registration dossiers. In their view, the low quality of registration dossiers demands a change in the CCH activities. The CCH strategy should include both "core" CCH activities and supplementary activities to increase the incentive of registrants to improve dossier quality.

Experience from other legislative areas should be considered. However, the solution(s) would need to be adapted to fit the REACH regulatory framework. Magnus Løfstedt presented two suggestions for potential complementary activities whilst highlighting that other solutions could also be relevant.

As an example of a successful "fame and shame" approach, he explained the "Smiley scheme" in the Danish food sector. Its purpose is to inform how well establishments comply with the rules and regulations, so consumers can make an informed choice on where to make their business. The Smiley scheme gives establishments an incentive to stay on their tiptoes and thus increases food safety. The approach is based on the fast publishing of inspection results, when they are both positive and negative.

Another example given were targeted campaigns to increase visibility and promote self-regulation. The purpose of such campaigns is to change the behaviour or mindset of the target group; not just the immediate effect from those that are "caught". Furthermore, the aim is to promote industry self-regulation and spontaneous updates of registration dossiers, to increase the visibility of ECHA, to target activities on areas that will have the highest impact (e.g. endpoints, substance types, use areas, etc.) and to improve resource efficiency for authorities.

Andrej Kobe from DG Environment presented the Commission services' perspective on CCH and its implementation. Their observations so far have been that ECHA and MSCAs have made a great effort to reach the 5% CCH target for the highest tonnage band dossiers submitted for the 2010 registration deadline. CCH has robust machinery and the deliverables are of high quality.

The consensus in the MSC is in general very high, yet it is informed and pursues the best result and maximum impact. The MSCAs' contributions have also been important. There have been dossiers that have been more challenging for the system such as UVCBs, categories, nanomaterials and one-generation reproduction toxicity studies, for the information requirements on which significant technical progress is taking place. Several innovations, most notably AoC-based CCH, have been successfully pursued. Andrej Kobe noted that based on the assessment of the 2010 registration deadline related dossiers, it is difficult to say something about dossier quality in general or for some dossier sub-categories. The 69% non-compliance figure for these dossiers as indicated by ECHA in its 2013 Evaluation Report causes concern but is distorted by selection bias.

The open question here is whether we are able to observe trends in dossier quality as they happen. Is CCH having a general impact or only on those dossiers addressed? How are other REACH processes impacted and catered for? Is CCH resource-effective? Can such resources (both ECHA and MSCA) be sustained over a longer period? Can or should they be stepped-up?

With regard to the elements of the strategy to be updated, Andrej Kobe indicated that the Commission services would like to see continued focus on the most relevant substances, to continue CCH on the highest tonnages and to use proxies for 'potential concern' such as a risk characterisation ratios close to 1. In addition, AoC CCH should be subject to the same selection criteria and objectives as other types of CCH. The elements of the selection and prioritisation criteria must enable multiple inputs such as previous evaluation experience (ECHA internal flags from testing proposal examination follow-up, substance evaluation or external risk management measure flags). The same selection and prioritisation criteria should be amenable to an approach by campaigns.

In addition, ECHA should not forget to address the relationship between individual and joint dossiers. Andrej Kobe suggested that targeted CCH should be the main approach as it is flexible in targeting the relevant information requirements. AoC scenarios could also be used as far as possible already in the registration process (pre-registration tools and completeness check). Full (overall) CCH should be used mostly in quality control or when pursuing specific objectives requiring consistency of the full dossier.

Andrej Kobe highlighted that complementary measures will often work in conjunction with the CCH, before or after it. Nothing should be excluded by default but these complementary measures should not be considered 'instead of' but rather 'with' CCH, sharing some of the common resources in synergy.

Planning of such actions should include external (MSCA) expertise as early as it is helpful. Andrej Kobe also indicated that CCH decisions need to be legally sound, clear and self-explanatory as well as being as short as possible. Quality Observation Letters (QOBLs) could also be used as a complementary measure. Sharing ECHA experience is important so that observations by ECHA's evaluating experts (flags etc.), which can be used for processes other than evaluation, need to be communicated to other parties. This requires IT Tools for ECHA and the MSCAs.

Follow-up is an integral part of the CCH procedures and there is an important role for Member States (MSCAs, MSEAs) and Forum. Here the open question is whether in the future similar 'prioritisation' will be required between the follow-up dossiers, or can all follow-up cases be handled. Quality control and indicators are needed to maintain transparency. There is a need to quantify data quality indicators. There is also a need to follow trends and to answer how CCH processes are delivering on data quality. This could be obtained by

using randomly selected full CCH results together with parallel manual screenings and ex-post analysis of all CCH element decisions and follow-up, and, for example, the impact of complementary measures. Satisfaction surveys could be launched and indicators on effectiveness in feeding other processes measured. Andrej Kobe also briefly indicated the role of the Commission in CCH.

In addition, the stakeholder observers gave feedback and observations on the implementation of CCH and offered their views on complementary actions to improve dossier quality. Erwin Annys of Cefic presented industry's feedback on compliance checks. The biggest surprise from CCH for industry has been the targeted compliance checks. This is because they give ECHA the possibility to go far beyond the 5% compliance check target as required by the legislation. This new CCH approach has created a certain loss of security for the registrants as every dossier can come back at any moment. The other aspect has been that companies can be overloaded with CCH (draft) decisions. Therefore, Erwin Annys recommended an open communication between ECHA and the registrants, as done for substance identity, as this can be very helpful. The biggest eye-opener for industry was the Evaluation Report 2013 reminding the registrants to keep the registration dossier up-to-date and be proactive as it is their duty to submit and maintain a compliant registration. The related recommendation for industry was to integrate REACH compliance into their quality management system. This was a surprise for many people working on a REACH level and even more at the CEO level where REACH was seen as a legislation where companies had to enter dossiers only at three moments in time.

In industry's view, the biggest mismatch in CCH is related to the use of REACH Annex XI to fulfil information requirements. The interpretation of this annex has been a major surprise for EU manufacturing companies and even more surprising for non-EU manufacturing companies. Therefore, communication outside of the EU on how to properly use REACH Annex XI would be beneficial.

Erwin Annys also made the following recommendations:

- ECHA communication on CCH draft decisions could be improved as the related legal or practical deadlines are very short and create a lot of frustration especially close to public holidays and other main holiday periods.
- In addition, ECHA's feedback on what has been considered acceptable in a registration dossier would be very beneficial but currently registrants only get feedback on what has been considered wrong in the dossier.
- Furthermore, commenting on the CCH draft decisions is only possible through webforms, followed by an automatic reply, which is currently received without content. Industry wishes to automatically get a copy of the comment submitted, as companies are dependent on a «print screen» approach to save their comment.
- Furthermore, a contact person in ECHA is not given for targeted compliance checks. This should be reconsidered at least for the more challenging endpoints.

Vito A. Buonsante from ClientEarth presented feedback and observations from the environmental, health and worker protection public interest NGOs on the implementation of CCH with the key question of whether the "No data, no market" principle is working as it should be.

This REACH principle provides in Article 5 that "substances [...] shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions[...]". Mr Buonsante referred to that based on the 5% CCH target deliverables by the end of 2013, 69% of dossiers examined by ECHA were not in compliance and 128 dossiers containing testing proposals out of 557 could not be processed due to inadequate description of the substance identity as reported in the 2012 Evaluation Report. He then asked how many substances have been excluded from the market due to these non-compliances.

Vito A. Buonsante also listed some incentives for registrants for non-compliance including that market access is secured regardless of information provided; only 5% of dossiers will be checked under CCH, there is no immediate consequence of non-compliance, the identity of a non-compliant company is protected and there is lack of enforcement. Therefore, he urged ECHA and the Member States to develop market incentives that allow only substances used safely to stay on the market. He also advocated for increased transparency to create such market incentives. He called for the use of REACH potential to make companies accountable, for a proactive enforcement strategy, to prioritise regulatory tools over voluntary ones, and to minimise incentives for non-compliance.

Third, Katy Taylor from the European Coalition to End Animal Experiments (ECEAE) highlighted the animal protection NGO's perspective on CCH. She raised issues regarding the quality of dossiers in terms of animal welfare, pointing out that good quality also includes appropriate use of non-animal approaches and failure to use validated alternative approaches is a quality issue, which should be addressed. She highlighted the need for education and enforcement to make it clear to industry and Member States which endpoints there are validated methods for, such as skin and eye irritation and skin sensitisation. In addition, she proposed to make it clear to industry when tests are not needed and to notify to a Member State (through a QOBL) if during a compliance check a registrant appears to have done unnecessary testing. Katy Taylor also raised some specific issues in compliance check decisions with regard to requesting reproductive screening tests and prenatal developmental toxicity tests and with regard to skin irritation studies to be done in vitro since 23 July 2009. She highlighted ways for ECHA and the MSC to help animal protection by inserting the "3Rs" recommendations into decision letters and to be more flexible at the MSC stage if new information becomes known.

In the plenary discussion, it was indicated by an industry representative that registrants would need some pre-warning or communication before an action campaign is launched so that they can plan the related work needed. Industry also wishes to have an option to give regular feedback to ECHA on the CCH decision-making process and other CCH process aspects.

In a separate closed competent authority session, Dana Rühl from the German competent authority gave feedback and observations on the implementation of CCH.

The subsequent competent authority plenary discussion reflected on potential enforcement related actions and also on direct enforcement actions without an ECHA decision. An MSCA representative indicated a wish to ask CCH to be launched by ECHA to support MSCA preparation of risk management options or based on national enforcement inspectors' feedback from their fieldwork. Several MSCA representatives also indicated a wish to launch more CCH on CSR issues and to develop with ECHA CCH related approaches and draft decision standard texts for such CSR issues.

3. CCH strategy 2014-2018 in light of ECHA's strategic objectives 1 and 2

3.1 BREAKOUT GROUP A: PRIORITISATION AND SELECTION OF DOSSIERS FOR CCH AND DOSSIER QUALITY IMPROVEMENT IN 2014-2018

Breakout group A reported on their discussions on the prioritisation and selection of dossiers for CCH and dossier quality improvement in 2014-2018. They discussed that dossier quality is needed to build confidence that the industry took responsibility to ensure and document the safe use of chemicals in the full supply chain and to provide authorities the basis for an informed decision on substances of regulatory interest. The group also discussed what the main concerns are and where dossier quality matters the most. The breakout group summarised the priority factors and highlighted that these may need to be combined (with several combinations). The priority factors are:

- 'So-called seven endpoints'[1] (as they trigger risk management measures, CLH and other risk reduction measures) and CSR.
- Uses by professionals (widespread(er), consumers' use as well); other widespread uses (open question: how to define this).
- Substances ending up in articles (consumer, environment), further zooming into certain 'high exposure potential' articles/functions of substances.
- Certain sectors/applications: such as maintenance, construction and metal sector.
- Groups of substances: similarity check (which substances are/are not similar enough).
- Most likely substitutes (to consider the timeline for filling the data gaps on primary endpoints).

The breakout group A highlighted the need to go for 'high(er) hanging fruits': properties, substances and uses not focused on so far. It is also important to consider what we would prioritise if we had the benefit of hindsight: how to identify new issues. However, if we do have sufficient information to ensure risk management measures and/or start risk management measures, then we should proceed. One important question is also whether we can find more cost-efficient areas with high improvement but low resource need (from all parties). Some concerns related to consumers are substances with data gaps in intrinsic properties (potential CMRs, sensitisers, EDs & PBTs) and exposure through articles (CMRs, EDs, e.g. in textiles, plastics) but also direct use of EDs, PBTs, nanos etc.

Sensitive consumers groups and consumer (mis)use of substances marketed for professional workers are also important here. Concerns related to workers are partly the same as for consumers: substances with data gaps in intrinsic properties - CMRs, chronic tox, sensitisers and EDs, e.g. due to (exposure-based) waiving, which hinder REACH/CLP and occupational health legislation to ensure substitution or control of risks. In addition high volumes, widespread uses, unclear description of uses, contradictory information on uses and exposure in registration dossiers are key factors. Based on current knowledge on occupational diseases, CMRs are a concern in the maintenance, construction and metal sectors. Professional workers need to be considered as a specific group. Good-quality REACH data will have an impact also on substances with outdated Occupational Exposure Limits.

Of special concern for the environment are substances, including degradation products, which have data gaps in intrinsic properties (PBTs, PTs, EDs) that hinder REACH/CLP (and environmental legislation) to ensure substitution or control of risks. Combined exposure from different sources (same substance, degradation

1 These are the following human health and environment related endpoints: genotoxicity, repeated dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, biodegradation and bioaccumulation.

products etc.) and exposure of humans through the environment (e.g. substances not relevant for the environment, but for human health) are important. Releases during the service-life and waste stage of articles need to be addressed, and further zooming into certain 'high exposure potential' articles or functions of substances is needed. Widespread use, e.g. plant protection product/biocidal product co-formulants and fertilisers, is of concern.

Group A gave an example of building a complementary strategy to improve dossier quality for classification issues. These could be cases where the registrant does not follow CLH or an identification of missing self-classification. An algorithm will be developed to identify such cases and shared with registrants. Then a letter campaign will be launched to note the inconsistences. ECHA would also 'help' MSCAs/NEAs to target and carry out enforcement (as a 'side product' of CCH and manual screening). These actions would finally result in the identification of substances that would require CLH.

The group also discussed drivers and incentives related to dossier quality improvement actions. It is important to promote the achievement of a good reference dataset to be used for REACH/CLP and other legislation purposes (by industry and authorities) and to use REACH information to ensure compliance with other legislation. The quality management system of a company could be one tool to get to a situation where good quality registration is self-evident. There is a need to get a snowball effect from the first 'icebreaker companies' which generate good-quality, fit-for-purpose registration dossiers by rewarding them. This attitude should become mainstream as the tools improve and the good model spreads, especially when the supply chains ask for better quality data (as nobody buys a substance unless the registration is acceptable).

One key question is how to create this multiplying effect. Suggestions include auditing the tools used by industry, and examples from a single CCH and learning lessons based on the MSC discussions to be communicated to (and used) by others. However, there is a need to clarify what a fit-for-purpose (good quality) dossier is, to give examples and differentiation depending on the parts of the dossier and types of case. It is also important that authorities use and take registration dossiers seriously and do not penalise good-quality dossiers with extensive data and 'favour' bad-quality dossiers with little information. The focus should be on the ends of the quality spectrum: the best and worst (prizes, name and fame/name and shame). There should be more awareness raising about the benefits of the good-quality registration leading to safe use. It was stressed that we all have a role to play and that the roles are complementary.

In the next steps, elaborating the prioritisation is needed in combining the priority factors, defining priorities in practice and identifying different tools and actions. There is also need to analyse effectiveness (including the resource needs and timespan) of the different actions. We also need to promote changes in behaviour and clarify the roles to identify who is responsible for what.

3.2 BREAKOUT GROUP B: COMPLEMENTARY MEASURES TO IMPROVE DOSSIER QUALITY

Breakout group B discussed complementary measures to improve dossier quality. It highlighted that understanding the root causes for non-compliance is important to help target complementary measures towards those areas where they can have the most impact.

One of the main causes for the high number of incompliant dossiers is that there is no immediate stick and no real incentive for compliance. This is considered by many to be a major contributing factor to non-compliance seen within dossiers. The registration number (= market access) is acquired with no assessment of compliance. The probability of the dossier being selected for compliance check is low (5%) and many are only partially checked.

The consequences for non-compliance (i.e. enforcement and penalties, revocation of registration number) have so far not been fully developed or used. The identities of non-compliant companies is not revealed by ECHA. Substances with non-compliant dossiers may be more difficult to identify as candidates for further regulatory risk management or substance evaluation. The group also discussed the related industry perspectives, including the misperception by industry (at CEO level) that there would be a need to respond only to the three registration deadlines (and not to keep dossiers updated). Some registrants are also on a steep learning curve, uninformed or dependent on other actors.

The group compiled a list of complementary measures supporting the REACH aim to ensure a high level of protection of human health and environment. The actions involve communication (including general communication and letter campaigns and their follow-up); REACH Article 36 decisions, technical completeness check, registration revocations, "fame and shame" approaches, capacity building and enforcement.

The group discussed the "fame and shame" approach in more detail. Its benefit is that it creates an incentive for registrants to strive for compliance through the use of market mechanisms. Fame is good reputation, which is important for companies. It increases transparency for the benefit of the general public and works in both directions, as both the carrot and the stick. It promotes a level playing field and influences market choice, leading to safer products and chemicals. However, the mechanism and criteria for their implementation would need to be developed. There are also risks involved e.g. challenges in court and liability claims. So, is it a measure to be taken up by a European Agency? A more integrated view on substance information under dissemination and ECHA decisions could provide a sufficient basis to draw conclusions. ECHA could publish information that would allow, for instance, NGOs to seek appropriate means to have a rating of companies. Clarification by ECHA might be useful to interpret results, such as companies with many registrations, scope of decisions (AoC, targeted) and severity of non-compliance.

There is a need for enforcement strategy and alignment. Enforcement of ECHA decisions is seen as a follow up action of non-compliance and not as a complementary measure. It is an essential part of implementing legislation but the lack of clarity on who does what may lead to inaction. The Forum for Exchange of Information on Enforcement has a key role in coordination. Enforcement authorities are on learning curve. Furthermore, REACH enforcement may not be at the top of the list in all Member States.

There is a need to consider sharing more information between ECHA and the Member States and a call for better clarity and coherence of figures in ECHA reports – the Article 54 report is difficult to interpret. The possibility of compiling information and communicating on enforcement actions and penalties should be considered. Openness from Member State enforcement activities is also important, as currently it is not possible to understand the full level of enforcement on REACH issues where these are enacted within individual Member States.

The use of enforcement and complementary measures was broadly supported by Group B and were seen as important and necessary elements to ensure compliance. The main recommendation of the group was to remove incentives to non-compliance and to award and recognise compliance. Transparency is one way to enhance compliance. Participants supported the need for enforcement and other measures. The main goal is to achieve overall compliance and to apply the correct selection of measures to achieve it. Dossier scrutiny is often a precursor for many future actions. There is also a need to retain and use the power of CCH where it is needed.

3.3 BREAKOUT GROUP C: OPTIMISATION OF CCH TO IMPROVE DOSSIER QUALITY

Breakout group C reported on their discussions on optimisation of CCH to improve dossier quality. The group discussed the types of CCH to be used (overall, targeted and AoC), where to use overall, targeted and AoC CCH, the scope (what to cover under overall CCH and what to cover under targeted CCH), how to

use random selection for CCH, and the best approach for specific CCH areas (CSR, read-across/categories, nanomaterials and intermediates).

Overall CCH should be used to address substances of highest concern. However, if the dossier data is poor, that also is of concern since it is not possible to know whether there is a risk or not. The group supported that Member States could ask ECHA directly to open cases for a limited number of CCH. ECHA could use AoC (or other) flags and IT profiling as selection criteria for the overall CCH.

Targeted CCH should be used to address specific needs in relation to substance identity, hazard data, chemical safety reports (CSR), read-across and nanomaterials. Targeted CCH should be aligned with complementary measure campaigns and could also serve substance evaluation (i.e. CoRAP). Member States could make suggestion for cases to be evaluated under targeted CCH. MSCAs can define the scope of such CCH (e.g. for potential CoRAP substances).

The majority of the group members supported the continuation of the AoC approach. An alternative proposal was to use the AoC algorithms only for the selection of cases for broader targeted CCH key areas. The group supported the application of the existing AoC scenarios all in one go as this will also save ECHA's resources. There was support to apply the substance identity AoC algorithm as a basis for a letter campaign, followed by substance identity targeted CCH if needed. AoC results can be used as a generic approach to give a base set view if a dossier has specific concerns and merits selection for targeted or overall CCH. ECHA will consult MSCAs later by written procedure on which new AoC endpoints/scenarios to develop.

There was support to continue using random selection for overall CCH. MSCAs expressed preference that the percentage of random CCH should be closer to 10 % rather than 20 %.

Participants supported the continuation of ECHA's current approach for CCH for intermediate dossiers and the Member States and the Commission expressed their support on the current CSR CCH approach. However, the resource implications of CSR CCH have to be considered. Substance evaluation may be a more comprehensive way to clarify concerns related to CSR. Member States are interested in ECHA's experience on CSR CCH, which will be gained during the decision-making process and follow-up evaluation.

Regarding enhancement of CCH on read-across/category approach containing dossiers the group supported ECHA's proposal for a dedicated read-across/category CCH workshop in Q4 2014. There was also support from the Member States to ECHA's approach for nano-related CCH and for ECHA to start a letter campaign before going to nano-related CCH.

3.4 BREAKOUT GROUP D: ENHANCED INTERACTION WITH MEMBER STATES TO IMPROVE THE EFFICIENCY OF THE CCH PROCESS

Breakout group D discussed the possibilities for enhanced interaction with Member States to improve the efficiency of the CCH process. The key elements discussed were improving the efficiency of the CCH and the related decision-making process, the possibility to discuss principle scientific and technical aspects of CCH draft decisions and the related decision-making process. Enhanced reporting of the CCH outcome, triggers from/towards other REACH/CLP processes, identifying trends of concern and preparation of recommendations for best practice, and the follow-up to dossier evaluation decisions were also discussed.

Regarding improving efficiency of CCH and the related decision-making process, it was noted that during the 30-day MSCA commenting period, it is difficult for MSCAs to react to a large number of cases. Both the timing and complexity of cases cause issues due to the limited MSCA resources. The MSCAs indicated that earlier intervention as well as discussion on critical issues is needed. The participants felt that it is difficult

to reduce the complexity of the process. However, MSCAs could for example let the ECHA Secretariat know which parts of the CCH process they wish to be involved in and contribute to. This would lead to effective use of resources to ensure maximum impact.

Group D also discussed how to best aid discussions on ongoing or open principle scientific and technical issues. It was discussed that it would be suitable to have such discussions in the MSC meeting, as this is the main discussion forum to decide on dossier evaluation issues. The MSCAs will consult their national experts for any potential discussion topics. The MSCAs also agreed that the ECHA Secretariat should invite MSCAs to contribute to certain selected scientific and technical topics, and certain substance discussions, early in the process. Such discussions and agreements at the MSC meetings would be expected to result in a reduced number of proposals for amendment. This is needed to gain efficiency in the process.

There is a clear need to enhance the reporting of the CCH outcome. The reporting should preferably encompass endpoint specific reporting. Such endpoint specific reporting could be useful for reporting, for example, in the Evaluation Report. ECHA noted that endpoint specific reporting would be difficult to extract and would require significant resources. The MSCAs agreed that if resources are an issue, ECHA should concentrate on dossier evaluation assessment over enhanced reporting. However, it was felt that to gain clarity in the information presented, ECHA could, for example, include a more extensive data analysis in the Evaluation Report.

With regards to triggers from or towards other REACH/CLP processes, an enhanced process of informing on the outcome of dossier evaluation together with a possibility to flag for subsequent REACH and CLP processes (for MSCAs to decide) needs to be established.

4. Discussion on the elements of the CCH strategy 2014-2018 and other actions to improve dossier quality

After the reports of the breakout groups, the plenary discussed key elements of the prioritisation for CCH and other actions together with optimisation of CCH and to improve dossier quality as part of the CCH strategy 2014-2018.

Increased transparency, communication and enforcement were highlighted as key aspects in other actions besides CCH to improve dossier quality. There was much support for the approach that CCH should be used as the last stick after other actions have been used to improve dossier quality. There is also a need to use "icebreaker" phenomenon by rewarding good industry behaviour and inspiring industry of such actions and get it established as a regular part and mainstream of business. Positive feedback to registrants on compliant dossiers is important here, for example, by disseminating the status and results of ongoing and completed CCH. This could be a further layer of ECHA's "neutral" transparency.

Communication of main expectations related to dossier quality related actions to company senior management is highly recommended. Member States need to think how they could use the "no data, no market" principle of REACH Article 5. When considering new actions such as "naming and shaming" a comparison of legal risks of such actions needs to be compared with the risks of registration dossier non-compliances. Furthermore, new actions also need to involve citizens and not only the chemicals business. Timing of actions to improve dossier quality needs to take into account other schedules such as when new non-animal integrated testing strategies become available. Cefic or other industry associations could arrange awarding the best quality registrant annually.

Furthermore, the plenary discussion indicated that the scope of a targeted CCH should addres all interrelated endpoints. Therefore, it was felt that the AoC and targeted CCH could, in the future, become very close to each other. In addition, ECHA could launch tailor-made targeted CCH and overall CCH supporting the complementary measures to be taken before CCH. The CCH process needs enhancement to become more efficient and effective. The continuation of the high number of ECHA letters and CCH decisions was highly supported. However, it should be kept in mind that a change in the risk management measures is costly for the registrant. Therefore, it is most efficient when addressing one of the six to seven key endpoints that registrants would consider if they need to address any other key endpoints.

After the MSCAs and ECHA have concluded their technical-scientific discussions on selected principal issues, it would facilitate the proactive improvement of these issues, if the outcome of the discussions is communicated to the registrants.

5. Conclusions of the workshop and next steps

Maximising the availability of high-quality data and creating incentives for better quality dossiers was one of the horizontal themes discussed in the workshop. There was great concern on the widespread non-compliance of dossiers and it was concluded that action by all parties is necessary. The very often referenced 69% non-compliance figure needs to be understood with the following context: there are different shades of non-compliance falling under this figure; some minor and some major non-compliances.

The active role of different actors is important. One of ECHA's strategic aims is to mobilise authorities to use REACH registration data intelligently to identify and address chemicals of concern. This requires enhanced linking of compliance check to other REACH and CLP processes, but this should work both ways. The efficiency and effectiveness of all upcoming related actions was frequently highlighted.

The following recommendations and conclusions were made at the workshop.

The workshop found a general agreement that the revised CCH strategy should concentrate on the right substances of concern relevant for safe use – both in the selection of substances for compliance checks and for other measures.

The workshop compiled ideas on the key selection priorities and factors. These will be analysed further in the follow-up to the workshop. Nevertheless, ECHA should not launch a massive machinery and process to finalise the priority setting scheme, but use a pragmatic, quickly moving approach.

Other actions besides CCH are necessary to improve dossier quality. There is a need to mobilise all actors to intiate such complementary measures. Such actions include communication, enforcement and pre-warning campaigns and registration revocations. These actions can be grouped by actors and there is a need to clarify better who should do what.

There are actions for industry to reinforce their initiatives to improve dossier quality and for the MSCAs to pick up their duties under REACH (there are also actions for ECHA on how to support them). The Commission could look better after the MSCA actions and report more on the penalties and enforcement actions made under REACH. Nevertheless, there are also actions for national enforcement authorities, and for NGOs who could launch awareness raising campaigns.

There is a need to better group these other measures to be used besides the CCH. Some, such as the completeness check, enforcement by Member States, guidance and advice, are fundamental elements of REACH. Others are clearly non-regulatory (letter campaigns etc.) and even "novel" ones (e.g. "name-fame-shame" concept).

ECHA is open to the proposals to use various measures and encourages all actors to consider how they can contribute. The workshop compiled a list of such possible actions to consider. ECHA will make a more detailed analysis of these possible complementary and other actions based on the workshop discussions. It is also of utmost importance to remove any disincentives for industry to improve dossier compliance.

Another principle of the updated strategy should be the effective and efficient use of different types of CCH and the use of different CCH types fitted for purpose. MSCAs wish to propose substances or dossiers to ECHA for CCH (or for other actions).

The availability of the required standard information is a key issue for the use of REACH registration data to intelligently identify and address chemicals of concern.

Furthermore, enhancement of interaction with the Member States will continue to improve the efficiency of the CCH process, including its follow-up phase. This requires increased interactive communication and early discussions on selected principle scientific and technical topics, and/or substances.

ECHA will look at the enhancement of CCH-related reporting to make it clearer, more readable and understandable. MSCAs agreed that if resources are an issue, ECHA should concentrate on dossier evaluation assessment over further detailed reporting. ECHA should better capture the flags from the follow-up evaluation and forward these to the relevant actors.

This all requires multi-annual planning and ECHA may need a couple of years for some new aspects to be implemented. Therefore, it is useful to think where we want to be in relation to the dossier quality status in the next five or 10 years. Dossier quality indicators are needed to monitor the trends.

ECHA will present elements for an updated strategy for discussion in the July 2014 CARACAL meeting and will inform the September ECHA Management Board meeting about the strategy.

The Chair noted that the workshop was very successful in discussing the elements for an updated strategy and mobilising all actors to plan actions to improve dossier quality. The Chair thanked all presenters, workshop organisers and participants for their active contributions.

6. List of Abbreviations

AoC	Areas of Concern
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 Disrupter
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
MSEA	Member State Enforcement Authority
NEA	National Enforcement Authority
QOBL	(ECHA) Quality Observation Letter
PfA	Proposal for Amendment
PBT	Persistent, Bioaccumulative, Toxic
PNEC	Predicted No Effect Concentration
RCR	Risk Characterisation Ratio
RMM	Risk Management Measures

RMO	Risk Management Option
SEv	Substance Evaluation
SVHC	Substance of Very High Concern
TPE	Testing Proposal Examination

Annex I – Agenda

Workshop on Compliance Check 2014 - 2018
– contributing to high quality of information for safe manufacture and use of chemicals

31 March -1 April 2014
ECHA Conference Centre, Annankatu 18, Helsinki, Finland

Monday 31 March 2014 Morning session Guido Sacconi Chair Leena Ylä-Mononen, Director of Evaluation		
8:30	Registration	
Introduction		
09:00	1.1 Welcome	Jukka MALM Deputy Executive Director, ECHA
09:10	1.2 Objectives of the workshop	Leena YLÄ-MONONEN Director of Evaluation, ECHA
09:20	1.3 Compliance check (CCH) in the context: Multi-Annual Work Programme 2014-2018 and ECHA strategic objectives 1 and 2	Jack de BRUIJN Director of Risk Management, ECHA
09:35	1.4 Outcomes and lessons from CCH 2009 – 2013	Leena YLÄ-MONONEN Director of Evaluation, ECHA
09:45	Discussion	
Feedback and observations from outside ECHA on implementation of CCH and views on complementary actions to improve dossier quality		
10:00	2.1 Denmark	Magnus LØFSTEDT, DK CA
10:20	2.2 European Commission	Andrej KOBE, DG ENV
10:35	Coffee	

11:00	2.3 CEFIC	Erwin ANNYS
11:15	2.4 Feedback from public interest NGOs	Vito A. BUONSANTE, ClientEarth Katy TAYLOR, ECEAE
11:35	Discussion	
11:50	2. 5 Germany (CA session[2])	Dana RÜHL, DE CA
12:10	Discussion continued (CA session)	
12:30	Lunch	
Afternoon session **CCH Strategy 2014-2018 in light of ECHA's strategic objectives 1 and 2 – general introduction for breakout group discussions** **Guido Sacconi** **Chair Leena Ylä-Mononen, Director of Evaluation**		
13:30	3.1 Strategic analysis of CCH and complementary activities in improving dossier quality	Wim DE COEN Head of Unit E1 - Evaluation
13:50	3.2 Introduction for breakout groups 4.a, 4.b and 4.c: Prioritisation and selection of substances for action with the aim to improve their dossier quality, and optimisation of CCH and complementary measures to improve dossier quality	
14:10	3.3 Introduction for breakout group 4.d: Enhanced interaction with MS to improve the efficiency of the CCH process	Mike RASENBERG Head of Unit C3 -Computational Assessment and Dissemination Margaret FEEHAN Team Leader, Evaluation Dana RÜHL DECA

2 Only for ECHA, MSCA and Commission representatives and ECHA Management Board WG and MSC members.

Breakout groups, Rooms: K176, K323, K324 and K325		
14:30	4. Practical arrangements of Break out groups	Hannu BRAUNSCHWEILER Team Leader, Evaluation
14:45	Group 4A: Prioritisation and selection of substances for action with the aim to improve their dossier quality (open group) Group 4B: Complementary measures to improve dossier quality (open group) Group 4C: Optimisation of CCH to improve dossier quality (CA session) Group 4D: Enhanced interaction with MS to improve the efficiency of the CCH process (CA session) Breakout groups can have their coffee break as best suits them in the afternoon.	All, Four breakout groups Chairs: 4A –Jack de BRUIJN, Director of Risk Management 4B - Leena YLÄ-MONONEN, Director of Evaluation 4C – Claudio CARLON, Head of Unit Evaluation 2 4D - Watze DE WOLF, MSC Chair
18:00	End of day 1	
18:00	Cocktail reception	

Tuesday 1 April 2014 Morning session MEETING ROOM Marie Sklodowska Curie Chair Leena Ylä-Mononen, Director of Evaluation		
09:00	Consolidation of reporting from the breakout group discussion (rooms K176, K323, K324 and K325)	All
10:00	Report back from the breakout groups A and B and discussion – Open session	Rapporteurs from 2 breakout groups
11:10	Coffee	
11:30	Report back from the breakout groups C and D – CA session	Rapporteurs from 2 breakout groups
12:10	General discussion on the elements of the CCH Strategy 2014-2018 and other actions to improve dossier quality (CA session)	
13:30	Lunch	
Afternoon session		
14:30	Reporting from CA sessions, conclusions of the Workshop and next steps	All
16:00	End of the workshop	

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