Minutes of the 14th HelpNet Steering Group meeting and regulatory workshops

Time: 2-4 April 2019

Place: ECHA Conference Centre, Annankatu 18, Helsinki, Finland

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REACH Workshop

1. Updates from ECHA

The Chair, Johan NOUWEN, opened the REACH Workshop by welcoming the representatives of the REACH national helpdesks (NHDs), observers from candidate countries, industry and the invited speaker, Elke SCHNEIDER.

The plenary session of the REACH Workshop was web-streamed for HelpNet members not attending the meeting, among them colleagues from the European Commission and the United Kingdom (UK). The names of the participants attending the REACH Workshop, the 14th Steering Group meeting and the CLP and BPR workshops are listed in Annex I to these minutes.

The Chair thanked the HelpNet members for their suggestions for the agenda of the first REACH Workshop of the year – e.g. recent developments on authorisation, safety data sheets after the amendment of Annex II to REACH, substitution, the upcoming Implementing Regulation on the operation of REACH after the expiry of the final registration deadline, and consequences of the UK withdrawal from the European Union. The agenda of the REACH Workshop was adopted without any comments.

The HelpNet Secretariat presented the status of the action points from the previous HelpNet REACH workshop on 1 February 2018, held back-to-back with the REACH 2018 Stakeholders' Day. All action points had been completed.

1.1 Update on the REACH review action points

Timo ROCKE (ECHA) presented the state of play of the REACH Review process and the follow-up actions applying to ECHA, Member States and industry. His presentation was a follow-up of the Commission's assessment and the action points presented to HelpNet participants in March 2018, at the 13th HelpNet Steering Group meeting.

The Commission published the results of the second REACH review[1] on 5 March 2018. The second REACH review concluded that REACH has significantly improved the protection of human health and the environment, promoted alternatives to animal testing, and ensured the free movement of chemicals on the EU market. REACH also contributes to the EU meeting the 2020 goal of the World Summit on Sustainable Development.

The Commission found that implementation of REACH is, however, lagging behind in meeting its political objectives, with shortcomings in the chemical safety information submitted by industry, especially with regard to long-term effects on human health and the environment and in relation to uses and exposure.

There were 16 concrete actions identified aiming to improve the quality of registration dossiers submitted by the companies, to simplify the overall authorisation process and to ensure a level playing field between EU and non-EU companies, to provide further support to SMEs, and to enhance enforcement by national authorities.

The outcome and the follow-up actions of the second REACH review were examined by ECHA and the Commission in May 2018, by the Management Board of ECHA, and at the Stakeholder Conference[2] organised by the Commission in June 2018. Discussions on recommendations continued at the CARACAL-27 meeting in June 2018 and are ongoing.

Timo ROCKE presented the mapping of all REACH action points and the ones affecting ECHA's Programming Document. The actions will be carried out together with Member States, ECHA and industry starting from 2019 onwards and are the following:

Action 1: Encourage updating of registration dossiers
Action 2: Improve evaluation procedures

[1] The second REACH review: https://ec.europa.eu/growth/sectors/chemicals/reach/review_is
[2] Stakeholder Conference on the second REACH Review, on 11 June 2018, in Brussels: http://ec.europa.eu/environment/chemicals/reach/past_events_en.htm

Action 3: Improving the workability and quality of extended safety data sheets
Action 4: Tracking substances of concern in the supply chain
Action 5: Promote substitution of SVHCs
Action 6: Simplification for a more workable authorisation process
Action 7: Early socio-economic information for possible regulatory measures
Action 8: Improve restriction procedure
Action 9: Further enhance Member State involvement in the restriction procedure
Action 10: Frame the application of the precautionary principle
Action 11: Interplay between authorisation and restriction
Action 12: Interface REACH and OSH legislation
Action 13: Enhance enforcement
Action 14: Support compliance by SMEs
Action 15: Fees and the future of ECHA
Action 16: Review of registration requirements for low tonnage substances and polymers

Question and answer session:

One NHD asked if the number of registration dossier updates has increased after the last registration deadline. Timo ROCKE mentioned that the number of updates of registration dossiers is still under expectations. The quality of registrations – as addressed in the Commission's recommendation and the BfR[3] report[4]- is clearly one of the key priorities for ECHA. Therefore, the topic will be discussed during the day and ECHA colleagues will provide more details on the process, including the number of registration dossier updates.

Regarding ECHA's report on action points and the concerns regarding the lack of compliance in registration dossiers with REACH information requirements – as also raised by national authorities in the last CARACAL meeting – Timo ROCKE confirmed that it is at the core of ECHA's Strategic Plan 2019-2023, translated into the Work Programme 2019 and can be anticipated to remain on the agenda for the work programmes in the years to come.

Furthermore, the Agency supports the Commission in identifying the extent to which an increase in the percentage of compliance checks for registration dossiers by tonnage band can be implemented.

1.2 Downstream users and communication in the supply chain

Monique PILLET (ECHA) gave a presentation covering two main topics: communication in the supply chain and the opportunity given by REACH Review Action 3 to work with the NHDs on improving communication in the supply chain; and support material for downstream users (DUs).

She highlighted the importance of communication in the supply chain and the three basic pillars of the chemicals legislation with regards to the safe use of chemicals, specifically the:

- Knowledge obtained at the registration phase.
- Regulatory action triggered by poor communication of information in the supply chain.
- Effective flow of information up and down in the supply chain.

The business-to-business communication chain should promote multi-directional communication, facilitating the flow of information up and down. Companies that use chemicals inform their suppliers about what they do with them, and in return, manufacturers and importers provide information on how to use them safely.

To ensure DUs receive more consistent and useful safety advice from their suppliers for their own uses, the ENES community5 has developed a suite of tools. Where needed, these tools will be further developed.

[3] BfR – the German Federal Institute for Risk Assessment.
[4] BfR and UBA concluding that one-third of REACH registration dossiers above 1 000 tonnes were likely not compliant with the information requirements.
[5] Exchange Network on Exposure Scenarios (ENES): https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

To better understand the current situation in the supply chain, ECHA has conducted different projects – interviews, market studies – with different partners, including the Commission, national enforcement authorities and NHDs. The key finding is that exposure scenarios (ESs) need further development to make their structure and content more recognisable and applicable for recipients. The findings of most of these projects will be published by the end of 2019 on ECHA's website.

The shortcomings of the extended safety data sheet have also been recognised in the REACH Review and Action 3 has been designed to address them. With Action 3, the Commission:

(1) encourages more industry sectors to develop and use harmonised formats and IT tools that would provide more user-targeted information and simplify the preparation and use of extended safety data sheets (SDSs), as well as facilitate their electronic distribution; and

(2) will consider including minimum requirements for the ESs for substances and mixtures in SDSs and request ECHA to develop a methodology for SDSs for mixtures.

As ECHA and the Commission cannot fulfil all these actions alone, the input from the HelpNet was welcomed.

Regarding the second topic of her presentation, Monique PILLET informed participants about a factsheet giving an overview of the support material for DUs, on ECHA's website[6]. The material on this page, largely available in 23 EU languages, helps companies to get familiar with the key aspects of the requirements for DUs.

She asked for feedback on the DU support material published in general[7], and specifically on a guideline which ECHA is developing to help users of NMP (1-methyl-2-pyrrolidone) complying with its restriction. For the guideline, she invited the NHDs to channel their comments through their respective competent authority, for the sake of effectiveness. Lastly, she informed, that there will be two posters available during the day where participants can leave their feedback.

The Chair noted that on ECHA's website, the REF-5 report[8] is already published, covering ESs, extended SDSs, risk mitigation measures (RMMs) and operational conditions (OCs). There are several recommendations made for industry, national authorities, the Commission and ECHA[9].

In the question and answer session, clarifications were given on several questions raised by HelpNet correspondents.

Concerning communication of DU uses, according to REACH, DUs need to check if their use is covered by the exposure scenario they received from their supplier. If this is not the case, DUs have several options; one of them is to assess their use by conducting a chemical safety assessment themselves.

If DUs choose this option, they need to inform ECHA. The CSR they develop for their own use is not part of the information they have to submit, but they have to keep it available for enforcement.

ECHA receives information about uses of substances, has an overview of such incoming information, keeps statistics on those uses and publishes them at least once a year[10]. This information is also available to the competent authorities.

ECHA is not communicating these uses to registrants as there is no request in the legislation to share this information with the registrants. But it is an element which helps ECHA to have a better understanding of uses of substances for various regulatory actions.

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[6] Factsheets: https://echa.europa.eu/publications/fact-sheets
[7] Downstream users information:
https://echa.europa.eu/regulations/reach/downstream-users
[8] Forum reports:
https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects
REF-5:
https://echa.europa.eu/documents/10162/13577/ref-5_report_en.pdf
[9] See Chapter 3.2 of REF-5.
[10] Overview on downstream user reports:
https://echa.europa.eu/regulations/reach/downstream-users/downstream-user-reports/overview-on-downstream-user-reports

Regarding the use of the Chesar tool, Monique PILLET replied that, indeed, in the past, Chesar was not used as much as expected, but now 50 % of the CSRs received with the dossiers are produced using Chesar, clearly showing a better implementation and use of the tool. Registrants have also discovered the benefit of using the Chesar tool to conduct the chemical safety assessments (CSA) and generate the report (CSR) as well as the ESs for communication in the supply chain. Chesar is also very convenient for updates of the CSR and the ES for communication.

Giving the example of the short guidelines developed for restrictions for professional uses developed for NMP, one NHD stressed the usefulness of these short guidelines. Monique PILLET replied that, at the moment, it is not known if a similar document would be developed for other substances.

Regarding the 'Forum SDS quality survey of 200 safety data sheets across Member States', it was further clarified that this is a joint initiative between the Forum and ECHA's accredited stakeholder organisations (ASOs). The national enforcement authorities have checked approximately 200 SDSs for deficiencies and ASOs will be invited to submit proposals during the course of 2019 on how to address these deficiencies. A workshop will take place in November 2019 to discuss solutions and suggestions, and agree on further actions.

1.3 Evaluation

Laurence HOFFSTADT (ECHA) informed participants on new developments on ECHA's evaluation processes which took place since her previous presentation at the 13th Steering Group meeting in October 2018. Ahead of the meeting, the Secretariat had informed the network of the new Q&As[11] related to changes in evaluation and of the new (support) documents offered to NHDs: updated practical guide[12], Q&As webinar[13], and a direct link to check the status of dossier evaluation.

The changes in the evaluation process were triggered by the REACH Review[14] made by the Commission in 2017, concluding that REACH is effective but not yet efficient, and new ways of accelerating data generation and increasing compliance need to be explored.

During the March CARACAL meeting, ECHA informed Member States about the upcoming action plan setting a higher ambition on compliance checks of registration dossiers. To make the evaluation process more efficient, a compliance check is performed on all relevant dossiers for a given substance and decisions are addressed to all registrants that have obligations to comply with the respective testing or required information given the tonnage bands registered.

Once the registrants receive the draft decisions for the joint submission (JS), ECHA encourages them to:

- Communicate with each other, submit consolidated comments on the decision and agree who will perform the requested testing;
- Ensure that the lead registrant is active and submits the dossier update containing the new/requested information, the chemical safety reports (where relevant) by the deadline indicated in the decision.

Changes due to tonnage downgrade or change of status are no longer taken into account after a draft decision has been sent: the registrants have to comply with the requests in the decision according to the tonnage or uses declared when receiving the draft decision. The same applies if the registrants wish to change the status of their registration from full to intermediate registration.

[11] Q&As updated on 21 March 2019: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Evaluation
[12] Practical guide: How to act in dossier evaluation: https://echa.europa.eu/practical-guides
[13] Information session on changes in dossier evaluation: https://echa.europa.eu/-/online-information-session-extending-dossier-evaluation-to-members-of-the-joint-submission
[14] REACH REFIT evaluation (REACH Review 2017): http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm

The type, scope and status of the assessment undertaken by ECHA on a given dossier is available to registrants and all interested parties on ECHA's website, on the 'Dossier Evaluation status' web pages[15]. Under the 'Content of table' and 'How to read the table' explanations, readers can find out if the evaluation of the dossier has formally started (status: 'under assessment') or if the draft decision was sent (status 'ongoing'). ECHA advises NHDs and the registrants to get familiar and monitor this table as needed.

Finally, Laurence HOFFSTADT presented some typical questions triggered by the new decisions.

One NHD asked if a decision template sent by ECHA to registrants would be available. Laurence HOFFSTADT explained that ECHA invested substantial efforts in 2018 to make the decisions more streamlined and clearer and that a template example is available in the presentation given at the 13th Steering Group meeting (Annex II, REACH Workshop, and action point 1).

Regarding changes in the tonnage band and the mandatory update of the registration dossier, Laurence HOFFSTADT reminded that even if a burden for companies, the update of the dossier should be done by companies as soon as new information about the substance is available (also the annual tonnage produced/imported). Companies should not be prompted to update their registrations because they receive a dossier evaluation decision, but must ensure that the data in their dossiers is always up to date.

As part of the action plan, ECHA is considering increasing the percentage of compliance checks for registration dossiers of each tonnage band. The exact figures would be confirmed once the Joint Action Plan between ECHA and the Commission is published[16], which is currently foreseen to happen in June.

1.4 Applications for authorisation

Thierry NICOT (ECHA) presented the state of play of applications for authorisation (AfAs) following the findings of the REACH review, two recent judgments of the European Court of Justice (ECJ) and three resolutions of the European Parliament (EP)[17].

ECHA and the Commission have gained a lot of experience since 2012-2013 when the authorisation process became operational. Since then, ECHA has received 130 AfAs, three review reports[18] and ECHA's Committees on Risk Assessment (RAC) and Socio-economic Analysis (SEAC) have issued more than 200 opinions. Statistics related to AfAs and review reports per year and per substance are available on ECHA website[19].

Currently, ECHA is studying, both internally and with the Commission, how the authorisation system would need to be adapted in the short and long term.

Overall, the authorisation system is improving safety: the study of the impacts on authorisation which was published as part of the REACH Review clearly showed that authorisation improves risk management measures, reduces exposure and has led to substitution of substances of very high concern. It also improves competitiveness and offers possibilities for innovative companies in the EU.

Thierry NICOT also covered DU notifications of authorised uses (Article 66(1) of REACH) following granted authorisations, review reports following expiration of authorisations, the upcoming peaks of authorisation RAC and SEAC opinions/COM decisions, and the new format to report[20] exposure data.

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[15] Dossier evaluation status: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

[16] Post meeting note: the REACH Evaluation Joint Action Plan was published on 24 June 2019: https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17

[17] See relevant articles in ECHA Weekly on 13 March 2019 and 10 April 2019: https://www.echa.europa.eu/news-and-events/e-news-archive

[18] To continue using the substance in question after the end of the review period, the authorisation holders may submit a review report.

[19] Statistics on received AfA and review reports: https://echa.europa.eu/received-applications

[20] Submitting downstream user notification of authorised uses: https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use

He also mentioned that new AfA Q&As were recently published on ECHA's website for:

- Transferability of applications and authorisation assets[21]
- Legal entity changes[22]
- DU notifications (Article 66)[23]
- Review reports[24]
- Updated AfA fees[25]
- Scientific research and development (SRD) (including *in vitro* diagnostic (IVD)[26] medical devices) and product and process orientated research and development (PPORD)[27]
- 4-NPEO/ 4-OPEO Annex XIV entries[28]

In addition, a practical guide on how to report legal entity changes in REACH-IT was recently published.[29] He also outlined the upcoming clarification expected from discussions taking place at the Commission and CARACAL level on intermediate uses exempted from authorisation, and on authorisation conditions/changes of circumstances. More developments may also be prompted by the new European Parliament resolutions on Cr(VI) authorisation and the European Court of Justice ruling on the lead-chromate pigments.

One NHD asked how the annulment of the authorisation on the lead-chromate pigments is impacting the DU notifications. ECHA and the Commission are still analysing the ECJ ruling and the Commission has the possibility to appeal by mid-May[30]

One industry observer asked if companies using Cr(VI) compounds will now have to submit their own applications and how many applications are expected. Thierry NICOT replied that it is difficult to foresee which will be the easiest way for companies to act after this recent court case and the resolutions from the European Parliament. The submission of several hundreds or thousands of single DU applications would be nearly impossible to manage. One potentially workable option could be joint submissions of AfAs by groups of homogeneous actors and businesses.

1.5 Restrictions

Stephen HOLLINS (ECHA) gave a brief overview of ECHA's ongoing work with restriction proposals, published and planned Q&As, developed guidelines on restriction entries and new features on ECHA's restrictions web pages.

He informed the participants that the restriction proposal dossiers currently in preparation by ECHA and Member States for opinion making in 2019 include those for tattoo inks, microplastics, polycyclic aromatic hydrocarbons (PAHs) and formaldehyde.

He informed participants on restriction Q&As developed and agreed with the Commission in 2018 and 2019 (e.g. the guideline on PAHs, perfluorooctanoic acid (PFOA), and the meaning of articles in restrictions entries). Furthermore, he elaborated on the planned 6th batch of Q&As which is based on the review of questions from individual companies on restrictions received by ECHA from 2017 to 2018, some enforcement issues identified by the Forum, and questions to ECHA from industry and the national competent authorities. Possibly, the batch will also include some Q&As on the new restriction on CMRs in textile articles.

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[21] Q&A IDs 1420-1422, 1428, 1466
[22] Q&A IDs 1239, 1242, 1247, 1248, 1250, 1253, section "(h)" in AfA Q&As
[23] Q&A IDs 1358, 1441
[24] Q&A IDs 1360-1370; see Section "(i)" in AfA Q&As
[25] Q&A IDs 600, 607; see Section "(d)" in AfA Q&As
[26] HelpEx IDs: 13937 and 14807
[27] Q&A IDs 585, 1442, 1443, 1498, 1565
[28] Q&A IDs 1566, 1567
[29] Practical guide: How to report changes in identity under REACH and CLP (Chapter 6): https://www.echa.europa.eu/documents/10162/13643/pg_legal_entity_change_en.pdf/09cb0bf2-4b27-4a44-8ed1-cd0fe39171e7
[30] See Section 5.2 of this document and HelpEx ID 16424

He explained the status of two guidelines, one on 1-methyl-2-pyrrolidone (NMP), which is under CARACAL consultation and which was found very useful by the participants; and the second one on nickel and its compounds on which the Member States did not reach consensus on terms of articles that would fulfil the criteria of prolonged contact with the skin, and thus the Commission and ECHA have decided to discontinue the preparation of the guideline; as the work has been discontinued, the draft nickel guideline will not be made available to NHDs or published on ECHA's website.

He then presented the new features of ECHA's web pages, namely (1) the registry of restriction intentions until outcome[31], where interested parties can follow the progress of a proposal through the restriction process, from the notification of the intention to the adoption of the final opinions by RAC and SEAC and the adoption of the restriction by the Commission, and (2) substances restricted under REACH[32]. For the latter, each entry shows a substance or a group of substances or a substance in a mixture, and the consequent restriction conditions, with links to directives/regulations (available in all EU languages).

ECHA has published new web pages dedicated to consumers[33] and to respond to the request from HD colleagues, some Q&As on restrictions are now grouped by product type. To help ECHA consider if further grouping is possible, participants were invited to provide comments on what groupings would be of most interest and the intended audience (REACH Workshop, action point no. 2).

2. Topics proposed by national helpdesks

2.1 The United Kingdom withdrawal from the European Union

István MÁK (ECHA) informed about the latest practical implications of the UK's withdrawal from the EU for REACH registrants and authorisation holders. This topic was an update to the recent HelpNet WebEx session on ECHA's support material[34] related to the UK's withdrawal held on 6 March 2019.

He emphasised that UK companies need to initiate the legal entity (LE) changes before the withdrawal date. The new date for the UK withdrawal from the EU is still subject to developments, but the so called 'Brexit window' will remain open at least till 12 April 2019 (23:00 GMT)[35].

After the withdrawal day, UK-based companies will no longer have access to their REACH and CLP assets, including those that were not transferred to an EU 27/EEA LE). Different scenarios for UK LE transfers to EU27/EEA are presented in detail in the Q&As available on ECHA's website[36].

During the 'Brexit window', all of ECHA's IT tools will remain available for UK companies and authorities. István MÁK explained the steps to be taken by UK legal entities and their EU27/EEA counterparts in relation to the UK's withdrawal and highlighted some areas of concern for duty holders.

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[31] Registry of restriction intentions until outcome: https://echa.europa.eu/registry-of-restriction-intentions
[32] Substances restricted under REACH: https://echa.europa.eu/substances-restricted-under-reach
[33] Chemicals in our life: https://chemicalsinourlife.echa.europa.eu/?utm_source=echa.europa.eu&utm_medium=display&utm_campaign=customer-insight&utm_content=homepage-quicklinks
[34] How will the UK withdrawal affect you? (support material on the ECHA website): https://echa.europa.eu/uk-withdrawal-from-the-eu
[35] After the meeting on 10 April 2019, the European Council agreed to a 'flexible extension' for the UK's withdrawal until 31 October 2019 at the latest. Any reference to the previous expected withdrawal date of 12 April 2019 means the actual date of the UK withdrawal in case there is no transitional period.
[36] Questions and answers for companies (new and updated Q&As published in 2019): https://echa.europa.eu/advice-to-companies-q-as/general
Q&A 1464 - Q&A 1417 - appointing an only representative within the EU-27/EEA
Q&A 1538 - acquisition, relocation to the EU-27/EEA, or intragroup transfer of the manufacturing activity
Q&A 1539 - importing business transferred to an EU-27/EEA-based legal entity

Importantly, downstream users in EU27/EEA may need to register the substance as importers if the UK legal entity fails to transfer their assets before the withdrawal date. In this context, industry observers expressed their concern with regard to interruption of supply chains given that some substances would remain registered only by UK-based companies. HelpNet members expressed the need to discuss this matter at the Forum, as some EU-27 companies will have registration obligations as of the withdrawal date. ECHA prompted the national helpdesks to make their customer aware of the list of substances registered by UK companies only. The list has been published on ECHA's website since 8 February 2019.

The uncertainty around the departure of the UK from the EU requires close monitoring from all involved parties to be able to provide up-to-date support. ECHA is prepared to update its supporting material and IT tools as needed, depending on further developments.

2.2 Implementing Regulation on the operation of REACH after the expiry of the final registration deadline

Alexis QUINTANA-SÁINZ (ECHA) informed on new developments regarding the Implementing Regulation, upcoming updates in ECHA's IT tools and support material available.

The transitional regime for registering pre-registered phase-in substances under REACH ended on 1 June 2018. To clarify how certain REACH provisions apply after that date, the European Commission has drafted an Implementing Regulation that was presented at CARACAL in December 2018. The inter-service consultation is still ongoing and the vote is planned for the June REACH Committee meeting.

The main issues to resolve in the Implementing Regulation are the transitional period for calculating annual volumes, submitting a registration with reduced information requirements and rules for data sharing. ECHA is preparing an update of the IT tools to reflect the situation after the cut-off date. For example, IUCLID and REACH-IT will be updated in November 2019.

Even if the inquiry number has never been a part of the completeness check as such, inquiring remains a legal obligation. Through the inquiry process, potential registrants are put in contact with the previous registrants and inquirers, have the identity of the substance foreseen for registration checked by ECHA and receive information about the (robust) study summaries submitted to ECHA.

The obligation to submit an inquiry serves the REACH objective to avoid unnecessary testing and in particular testing on vertebrate animals.

While it is a legal requirement to inquire, ECHA does not have a legal basis to prevent a company without an inquiry number to register. Potential registrants who have contacted the lead registrant and who have received a token could join the joint submission without inquiring.

As the content of the Implementing Regulation was not concluded at the time of the meeting, there were certain aspects that could not been clarified or answered during the event. Nevertheless, it is clear that the relevant guidance documents, manuals and Q&As will be updated to reflect the changes triggered by the Implementing Regulation and the post-registration phase.

3. Break-out groups

In this session, HelpNet members brainstormed with ECHA experts on how to support companies in keeping their registrations up-to-date, what kind of role the helpdesks could have in supporting companies in their substitution activities, and how to support the efforts to make exposure scenarios a useful tool for recipients in the supply chain.

3.1 Registration dossiers updates and post registration actions

Catherine CORNU, István MÁK, Virve SIHVOLA, and Ana VALLEJO CORTES (ECHA), moderators of this session, introduced to the participants the topic and the main objectives:

- To highlight that a registration dossier is a dynamic document and it is a legal duty to keep the dossier updated.
- To gather feedback on hot topics.
- To introduce the new OR account type in REACH-IT and discuss about possibilities to simplify ECHA's IT tools.

The HelpNet members have received surprisingly few questions regarding dossier updates. The general reasoning behind seems to be that companies (particularly SMEs) consider the last registration deadline as the fulfilment of registration duties. Large companies are more aware of the duty to update their dossiers and do it spontaneously.

There were divided opinions among members on the reasons that trigger dossier updates. Most reasons are on the industry side (e.g. new use, composition, source, impurity, tonnage). The changes of information requirements as triggers for updates were also discussed. If making an update would be a recurring exercise, a tick box in REACH-IT would be helpful. However, the majority agreed that updates are needed when new information becomes available, not as a recurring exercise.

The upcoming amendments to REACH information requirements for nanomaterials in 2020 were also raised for discussion. This would require companies to assess whether the new information requirements apply to their substances in nanoform and trigger an update. One NHD highlighted the importance to communicate on dossier updates and proposed that direct emailing through REACH-IT could be used for this kind of campaign. It was also pointed out that a banner could increase the visibility of the information already available on the website (Step 7 - Keep your registration up to date).

In one Member State, a lawyer in a private practice has published an article in a journal, according to which a change of annexes would not trigger dossier updates for existing registrants. The question is under discussion in that Member State. In ECHA's view, the update obligation also applies to existing registrants, because the registration obligation for nanomaterials existed from the outset, and the amendment of Annex VI is designed to specify how the required information is submitted by existing and future registrants. There is no retroactive effect, where the information requirement concerns current registrants. ECHA also points out that there was a unanimous understanding that the amendment of the information requirements on the two-generation study applies to all existing registrants. No one had made this legal argument in any of the other Member States. In another one, the helpdesk will organise a workshop on the quality of dossiers, expecting to get feedback from companies regarding their intention to update their registration dossiers.

The new account type for ORs planned for one of the future REACH-IT updates was introduced to the participants. The reason for this change is to make a clear difference between the roles of manufacturer/importer and OR. It will support capturing all registrations, declaring the correct company size and avoiding mixing roles. It will also facilitate the process of changing ORs through the legal entity change functionality.

The simplification of the IT tools is highly appreciated and will most likely increase the willingness of industry to update their registration dossiers. The administrative tasks can be simplified but scientific parts, such as hazard characterisation, will remain as they are.

3.2 Substitution

Thijs DE KORT (The Netherlands), **Denis MOTTET, Christina LOUKOU** and **Olena KRYCHEVSKA** (ECHA) moderators of this session, introduced to the participants the topic and the main objectives of this interactive session:

- To discuss the experiences of NHDs on substitution.
- Gather feedback on different ways the NHDs are dealing with this topic, the

substitution activities/initiatives at national level and future plans.

- Inform on the implementation of ECHA's substitution strategy and on the support ECHA and Member States are providing to stakeholders.

The HelpNet members reported that they have received very few questions on substitution. Possible reasons for this could be that substitution issues are dealt with by other national organisations, substitution can be resource-intensive for companies, and/or reluctance by companies to share confidential business information. Some questions received are requesting information on how to substitute in the most effective way, how to search for alternatives, how to find partners, experts, projects and/or funding. It was observed that the Candidate List and REACH Annexes XIV/XVII updates have triggered questions on substitution (e.g. for Cr6 substances).

It was discussed that the role of the NHDs is primarily to address substitution-related questions related to regulatory processes (e.g. authorisation, restrictions) within their remit and to facilitate access to substitution resources, but not to provide technical advice on substitution. Many NHDs highlighted the importance of promoting substitution already at an early stage, upon inclusion of substances in various lists (e.g. Registry of Intentions, Candidate List), to avoid regrettable substitution, by informing proactively about public consultations on alternative substances/ techniques and the possible stringent legal requirements of risk management that may arise (e.g. authorisation, restrictions).

Some NHDs are more proactive in substitution matters, developing dedicated web pages on substitution, pointing to ECHA's substitution web pages[37] or to supporting material by industry associations, informing on substitution matters through newsletters[38], involving advice of technical experts/researchers, participating in events (e.g. Green Chemistry conferences, supply chain workshops), raising awareness on substitution activities using information campaigns, through collaboration with national inspectorates, and through involvement in joint projects on substitution with national organisations/research institutions.

Regarding possible ways forward in dealing with substitution, it was mentioned that supporting companies in substituting hazardous substances could be considered as one of the aims of the national helpdesks. The importance of closer collaboration between NHDs, ECHA and other stakeholders on substitution issues was emphasised, as well as the need for more targeted campaigns tailored to the needs of specific sectors, in collaboration with industry organisations. Proactive actions by NHDs could include the awareness raising on the importance of substitution and safe-by-design approaches and guiding companies towards existing resources to support them concretely in this challenge. This could be done by informing companies about generic or targeted substitution events or projects, substitution-dedicated websites (e.g. gathering substitution methodologies and cases stories), sharing best practice to overcome substitution challenges, promoting successful examples of substitution, pointing companies to substitution networks and partners, facilitating contact between researchers and companies, engaging companies in supply chain communication, supporting voluntary initiatives on safer and sustainable chemicals/technologies, sharing information about funding possibilities to ease the financial burden, and exploiting synergies with other chemicals legislations (e.g. OSH).

Lastly, it was highlighted that a change of mindset at company level is necessary, putting substitution and safe-by-design approaches in a bigger perspective by emphasising their benefits in offering a competitive advantage to companies, as well as in protecting the environment and the health of workers and consumers.

3.3 Downstream users and communication in the supply chain

Monique PILLET, Outi TUNNELA and **Pedro ROSELLÓ VILARROIG** (ECHA) the moderators of the break-out group introduced the topic to the participants.

[37] ECHA's substitution web pages: https://echa.europa.eu/substitution-to-safer-chemicals
[38] See also article in ECHA's newsletter (November 2018): https://newsletter.echa.europa.eu/home/-/newsletter/entry/from-substitution-to-safe-design

The ENES network has been working since 2011 to identify good practices on preparing and implementing exposure scenarios, and to develop effective communication in the supply chain. Action 3 of the second REACH Review also focuses on this topic and is an opportunity to set common goals and motivate all stakeholders to cooperate to achieve them.

The main objectives for addressing this topic were:

Firstly, to present the a summary of the Commission's kick-off workshop on the REACH Review Action 3 in which the Commission, Member States and industry discussed current practices in preparing extended safety data sheets and gathered ideas on how they could be improved.

Secondly, to understand how to involve OSH and environmental authorities in Member States; if the NHD already works with them or knows them, and explore possibilities for collaboration, and who ECHA could potentially contact in Member States. Finally, if the correspondents or NHDs themselves can be involved, settle how this can be done.

Andrew MURRAY (ECHA) focused the discussion on three points:

1. User targeted information: information in the exposure scenarios (ESs) should be tailored differently to the formulators and to the end-users of the supply chain.
2. Minimum requirements for ESs, for substances and for mixtures. While there is something along these lines for SDSs (Annex II to REACH), only dispersed references are made to the content of ESs in the legal text.
3. Methodology for SDSs for mixtures – already some available, but with a limited scope.

The open discussion led to some comments and conclusions around these aspects and beyond.

It was acknowledged that the safe use of mixtures information (SUMI) for end users is useful in some cases, and the lead component identification methodology (LCID) for others. Therefore, these methodologies are complementary.

It was pointed out that SEVESO and waste legislation overlap with REACH requirements in this regard. There was an understanding that harmonising or aligning assessment concepts in REACH, OSH (Occupational Safety and Health) and environmental legislation would allow for a more efficient transfer of information, making it easier for industry to comply with all of them.

A point on affordability was also made. The ESCom[39] standard phrase catalogue does not fully cover the ESs, which therefore also contain free text. This lack of harmonisation makes translation very costly.

There is a lack of knowledge, or awareness, on upstream communication duties. Some SMEs even struggle with the SDS alone, requesting a basic IT-based template to start with. Another challenge for SMEs is the specific knowledge or expertise on Chesar, ECETOC-TRA and any other tools available for chemical safety assessment. In that context, it was noted also that Chesar is currently intended for registrants.

On a higher level, some participants pointed out that the concept of a dynamic ES that would use an electronic transfer format for eSDSs would work better than the traditional paper or PDF format. This would allow DUs to choose by themselves the information relevant for them and it would help them to use the information for chemical safety at the workplace. However, the participants felt that currently the SDSs are not efficiently used but just archived and they are not necessarily even utilised as a part of companies' training programmes for newcomers.

Closing of the REACH Workshop

The Chair thanked all REACH participants for their active and valuable contributions to the workshop and invited them to the 14th Steering Group meeting on 3 April 2019.

[39] Exposure scenarios for communication

The 14th HelpNet Steering Group meeting

1. Opening the Steering Group meeting

Johan NOUWEN (ECHA), the Chair of HelpNet, opened the 14th HelpNet Steering Group meeting by welcoming the REACH, CLP and BPR national helpdesks (NHDs), observers from candidate and third countries, industry observers including the new observer SMEunited, and invited speakers, Elke SCHNEIDER and Renato CABELLA. HelpNet members not attending the meeting, among them representatives of the European Commission and the UK, could follow the event remotely.

The names of participants attending the 14th HelpNet Steering Group meeting and the regulatory workshops are listed in Annex I to these minutes.

1.1 Opening by the Chair of HelpNet

Johan NOUWEN explained that his responsibilities within the Agency have changed due to the reorganisation of ECHA, and this is the first time he is chairing the Steering Group meeting as the successor of Andreas HERDINA.

ECHA's new organisational structure[40] entered into force on 1 January 2019, and aims to support a more flexible way of working, facilitate the implementation of ECHA's new strategy and staff development as well as enable ECHA to take on more tasks, and pieces of legislation. The new structure of ECHA is no longer based on processes, but is competence-oriented.

The HelpNet and the Forum activities are now situated in the 'Directorate of Submissions and Interaction' in the unit 'Support and Enforcement'. In the new structure, guidance activities have been decentralised and allocated to the responsible units in the organisation. Detailed descriptions of the new directorates and units[41] are available on ECHA's website. As of 1 June 2019, the new Head of Unit of the 'Support and Enforcement' unit will be Erwin ANNYS.

One HelpNet member remarked that the reorganisation of ECHA would trigger the update of the HelpNet Handbook, specifically the section nominating the chair of the HelpNet Steering Group, stating that 'ECHA's director of the directorate in charge of the HelpNet Secretariat is the Chair of the HelpNet Steering Group'. Johan NOUWEN replied that, following Andreas HERDINA's retirement and as announced on ECHA's website, he had been appointed as the new Chair of the HelpNet. The HelpNet Handbook would be revised to reflect this change (HelpNet Steering Group, action point no. 1).

The Chair expressed that he wants to work closely with the HelpNet as the new Chair of the network and increase the potential of the network by new means of cooperation, exchange of good practices, and make the needs of the network known to ECHA. On behalf of the Regulatory Support team and the HelpNet Secretariat, the Chair expressed his support in bringing topics of interest to the agenda of future Steering Group meetings and workshops.

Jukka MALM, Deputy Executive Director of ECHA, Director of the 'Submissions and Interaction' and coordinator of 'International Activities' also welcomed the participants, and expressed his full support to the network for future activities and to Johan NOUWEN in his new role.

1.2 HelpNet 13 - follow-up of action points

Viorica NAGHY (ECHA) presented the list of action points from the previous Steering Group meeting. All action points were closed. The action points related to national helpdesks expressing

[40] Organisation of ECHA: https://echa.europa.eu/about-us/who-we-are/organisation
[41] ECHA's directorates and units: https://echa.europa.eu/about-us/who-we-are/directorates-and-units/directorate-a

their interest in inviting ECHA to visit their helpdesk or to visit ECHA in 2019 were closed with the presentation of Laura WALIN (agenda item 7.2).

1.3 Approval of the HelpNet 14 draft agenda

The Chair asked the participants if they have any comments on the updated draft agenda of the Steering group meeting uploaded on S-CIRCABC on 27 March 2019. In the absence of any comments or any other business points for discussion, the agenda of the meeting was approved.

The Chair requested the HelpNet members to verbally express their concerns[42] (if any) on the attendance of observers or invited speakers at particular agenda points. No objectives were raised.

2. Integrated Regulatory Strategy and the new Group Management approach

Hannu BRAUNSCHWEILER (ECHA) gave participants an update on the Integrated Regulatory Strategy[43] and the new group management approach, describing how the strategy and grouping of substances[44] fit into ECHA's strategic plan for 2019-2023.

In implementing the strategic plan, ECHA will focus on:

1. Identification and risk management of substances of concern.
2. Safe and sustainable use of chemicals by industry.
3. Sustainable management of chemicals through the implementation of EU legislation.

To identify and conclude which substances are of concern and which have a low priority, and to identify the most effective regulatory risk management actions to be taken, ECHA is working together with Member State competent authorities (MSCAs) and the European Commission. By pooling together all hazard information for related substances, it might be possible to conclude on the need for action, despite data gaps for individual substances. Another benefit of working with groups of substances is that the grouping approach increases the predictability of authorities' actions and supports substitution.

The group assessment is currently done by ECHA and the grouping itself is based on structural similarities, read-across arguments in the registration dossiers, already known groups from previous work and by using IT algorithms and expert judgement. The work is ongoing and communication to MSCAs will take place through the Activities Coordination Tool (ACT), the risk management and evaluation (RIME+) platform[45], and S-CIRCABC. Communication to industry and the general public is under revision and ECHA's web pages will be updated with information on the Integrated Regulatory Strategy and working with groups of substances by the end of 2019.

The plans and the first outcomes of the group management approach are already visible for MSCAs through regular status reports in the Rime+ Bulletin. For stakeholders and the general public, this information will be available by the end of the year through the updated web pages.

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[42] According to the Handbook, Section 1.2 'The Chair of the HelpNet Steering Group considers and takes decisions on any objections from members to the participation of observers or additional experts. The Chair may decide, for example, that the latter may not follow a specific agenda point, or that a closed session is held'.

[43] ECHA Integrated Regulatory Strategy web page:
https://echa.europa.eu/echa-irs

[44] ECHA Q&A on 'Screening of substances of potential concern', subsection on 'Substance grouping':
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Screening+of+substances+of+potential+concern

[45] RIME+ platform:
https://echa.europa.eu/rime

3. Practical implications of the UK withdrawal on the operation of HelpNet

The Chair presented the practical implications on the operation of the HelpNet and the monitoring activities conducted by ECHA related to the UK's withdrawal from the EU.

During the UK withdrawal process from the EU, ECHA discontinued inviting representatives of the UK to ECHA meetings (physical or online) taking place after 30 March 2019. However, due to the new circumstances[46] developing – more particularly postponement of the UK withdrawal from the EU – in the days before the 14th HelpNet Steering Group meeting and the regulatory workshops held from 2 to 4 April, representatives of the UK were invited[47] to these events.

With the announced date of the withdrawal, the UK would become a third country and it would no longer have any representatives sitting in the ECHA bodies or networks, such as the Management Board, Committees, Forum or the HelpNet.

Importantly, this would also apply if a transitional period would be agreed by the UK and the EU. If the date of withdrawal would be postponed, ECHA will follow the further guidelines from the Commission. The access to ECHA's IT tools and S-CIRCABC will be disabled on the date of withdrawal. ECHA's website, including information on the national helpdesks, will be updated to reflect the UK's status accordingly.

The Chair also presented statistics on questions arriving at ECHA related to the UK's withdrawal.

4. Updates from the HelpNet Secretariat

4.1. Report of national helpdesk 2018 activities

Viorica NAGHY (ECHA) presented the main findings from the national helpdesk 2018 activities report, covering the activities carried out by national helpdesks from 1 January to 31 December 2018. The HelpNet Secretariat collected the information between January and February 2019 through a survey, from national helpdesks of 28 EU Member States, Iceland, Liechtenstein and Norway (HelpNet members), Serbia and Montenegro (as observers from EU candidate countries), as well as the Swiss BPR and CLP helpdesks (as third-country observers). In total, 54 national helpdesks from 34 countries replied to the survey.

• Total number of enquiries

In 2018, NHDs received around 50 000 enquiries from their customers, of which 42.4 % were related to BPR, 31.2 % to REACH and 22.0 % to CLP. The remaining 4.4 % were reported without being allocated to a specific regulation.

• Enquiries by regulation

In 2018, the overall number of enquiries slightly decreased compared to 2017, but remained the second highest number of questions ever recorded. The number of REACH questions remained at the same level as in 2017, reflecting the workload related to the REACH 2018 registration deadline. A decrease was observed in the number of CLP questions and there was a slight increase in the number of BPR enquiries.

[46] Following the European Council Decision taken in agreement with the UK, the period under Article 50(3) of the Treaty on European Union was extended until at least 12 April 2019: https://data.consilium.europa.eu/doc/document/XT-20006-2019-INIT/en/pdf
After the meeting on 11 April 2019, the European Council decided in agreement with the United Kingdom that the UK remains a Member State until the 31 October 2019.

[47] As an alternative to the physical meeting the HelpNet Secretariat webstreamed the events, offering the representatives of the UK and other HelpNet members the possibility to follow the events remotely, excluding the break-out groups and the CLP workshop.

• Resources

Regarding available resources, the majority of NHDs reported that they had not changed compared to the previous year. In 2018, only one BPR helpdesk reported additional resources compared to 2017. In contrast, five REACH, four CLP and five BPR helpdesks faced resource cuts. Typical reasons for this were either staff leaving the organisation, or resource allocation to other tasks.

• Time for answering enquiries

The time for answering enquiries is generally below 10 days, and there is a deadline agreed by most of the countries to provide an answer to the customer without undue delay. For some NHDs, the national law requires an answer in 60 days, while for others the time is much shorter. Nevertheless, the reply time depends on the complexity of the question.

• Hot topics

For REACH, the hot topics have changed slightly compared to those of 2017. The first four positions remained the same, though the rankings have changed. Noticeable changes have been observed with the topic 'Complying with restrictions' which dropped to 10th position and with 'Data sharing and joint submission' and 'Only representative's obligations and duties' which were no longer among the top 10 hottest topics. New topics appearing among the top 10 hot topics were the 'REACH 2018 registration deadline' and 'Scope of REACH', indicating an increased awareness of companies with respect to their obligations under REACH.

For CLP, two constant hot topics continued to be 'Labelling' and 'Classification and labelling of mixtures'. As expected, the new Annex VIII to the CLP Regulation, on information related to emergency measures ('Annex VIII (future obligations)'), moved up to second place on the list of hot topics in 2018 as both ECHA and the NHDs have started awareness-raising actions towards duty holders with a view to preparing them for the first notification deadline in January 2020.

In general, the picture of BPR hot topics at the national helpdesks remained much the same in 2018 compared to 2017. 'National procedures' in first place and 'Transitional period' second were by far the two most frequent topics. The third to seventh positions covered topics with similar rankings as in 2017 such as: 'Authorisation', 'Fees', 'General obligations under BPR', 'Mutual recognition', and 'Active substances', while 'Article 95' moved up to eighth position.

In 2018, 'In situ generation' and 'Classification and labelling' represented new BPR hot topics compared to 2017, replacing 'Treated articles' and 'Submissions and IT tools'.

• Involvement of HelpNet members in other committees, networks, expert groups of ECHA and the European Commission

Members of the HelpNet are involved in numerous bodies of ECHA or the Commission, the highest percentages for participation were reported for the Biocidal Products Committee (44 %), RAC (40 %), SEAC (33 %), the Communicators network (27 %), Competent Authorities for REACH and CLP (CARACAL) (25 %) and the Competent Authorities for Biocidal Products (24 %).

The national REACH, CLP and BPR helpdesks report on their activities, workload and particular needs every year. Until last year, the annual report was published on S-CIRCABC only. Since 2018, a short version of the report is published on ECHA's website. After the meeting the HelpNet Secretariat will launch a written procedure to seek HelpNet members' agreement on the public version of the '2018 Report of national helpdesk activities'.

In the Q&A session, clarifications were given on the highest number of enquiries received by one Member State. The high number of CLP-related questions reported by one national helpdesk was triggered by the large number of questions on poison centres, enquiries related to the transitional period and Annex VIII procedures, and numerous enquiries received from customers after the REF-5 awareness raising.

4.2. Simplified FAQ procedure

Viorica NAGHY (ECHA) introduced the simplified FAQ procedure, a pilot project started in 2017 by REACH members. Ahead of the 2018 REACH registration deadline, REACH members discussed how to make the FAQ process leaner and quicker to strengthen communication and cooperation amongst the HelpNet correspondents. They agreed on a process with shortened commenting rounds for questions related to the 2018 deadline.

The results of the pilot project were presented to the participants, who discussed the criteria for skipping the second round of consultation. Clarifications were given on the way ECHA is assessing the suitability of the FAQ proposals, how HelpEx access rights are given to observers to the FAQ platform, and on the minimum number of members providing feedback on a Q&A proposal required for skipping the second round. Some NHDs expressed their wish to consult their colleagues in the national helpdesk, and provide their final opinion through written procedure.

It was agreed that the HelpNet Secretariat will launch a written procedure after the meeting seeking the members' and observers' opinions on the proposed simplified FAQ procedure.

4.3 HelpEx improvements

Sorina PARASCHIV (ECHA) presented the **Improvements of HelpEx** planned for 2019.

At the 13th HelpNet Steering Group meeting, HelpNet members expressed their opinion about the usefulness and effectiveness of the existing tools and means of communication in HelpNet. The HelpEx tool gave rise to most of the comments and requests for improvement. Participants expressed that they would appreciate a friendlier, more intuitive user interface, and increased search functionalities.

The improvements proposed to be implemented in 2019 were:

- A new layout of the main page of the HelpEx console.
- Resizing the existing fields on the main page.
- Thumb up/down feedback button (optional).

With some improvements under discussion:

- Single box for free text searches.
- Notification email including the direct link to the corresponding question in HelpEx.
- Automatic retrieval of passwords.

To align the HelpEx tool with the internal one (Remedy) used by the ECHA Helpdesk, some changes will be visible in HelpEx on the categorisation of questions by topic/regulation. For the biocides questions, the list of 'processes' and 'keywords' will be updated with the new values[48].

Discussion on the proposed features took place. The usefulness of the thumb up/down button was recognised for FAQs and BPR-scope questions. For REACH and CLP, HelpNet members would appreciate an explicit feedback provided on the content of the Q&As posted as a sign of active involvement of the national helpdesks.

4.4 New observer in HelpNet - SMEunited

The Chair introduced **Malte-Matthias ZIMMER**, nominated to participate in the HelpNet Steering group meeting on behalf of SMEunited, and to present the support activities provided by SMEunited to industry. He told that Malte-Matthias Zimmer is familiar with the REACH and CLP regulations, and with the needs of SMEs with respect to information and enforcement.

[48] New values for the processes drop down list: Renewal, In situ active substance (AS), Treated article, Change regulation, Same biocidal product, Parallel trade, Information requirements, Transitional measures, ED (endocrine disruptors) properties.

According to the HelpNet operating procedures, the Secretariat sought the HelpNet members' agreement on the participation of SMEunited in the work of the HelpNet as an observer. The written procedure was conducted from mid-December 2018 to 18 January 2019 and resulted in a favourable opinion and an invitation to SMEunited for the 14th Steering group meeting.

SMEunited, known as UEAPME until November 2018, represents the interests and perspective of SMEs at European level. This European SME umbrella organisation incorporates 67 member organisations, representing altogether 12 million enterprises with nearly 55 million people employees across Europe.

SMEunited is represented by national experts in several committees at EU level, for example in CARACAL, Forum, and the REACH Nanomaterials Working Group.

Some of the SMEunited members were introduced: the Austrian Federal Economic Chamber (WKÖ - Wirtschaftskammer Österreich), the Skilled Crafts Organisation (ZDF - Zentralverband des Deutschen Handwerks), the French Chambers of Commerce and Crafts (CMA - Chambres de Métiers et de l'Artisanat), and the European Committee for Surface Treatment (CETS). These organisations provide support services to companies, transfer of knowledge on different pieces of regulations, translate documents and prepare presentations and publications, and participate in (online meetings) meetings and workshops.

Malte-Matthias ZIMMER highlighted the difficulties experienced by SMEunited in reaching 12 million enterprises, providing different information targeted to different kinds of interest, and on different pieces of legislation, assuring a top-down and bottom-up flow of information, as well as making translations required by different sectors available.

The structure of different member organisations – e.g. ZDF with 53 craft chambers, 48 trade associations, and around 130 professions – requires that information and messages are understood by SMEs, as many of them do not master English. Consequently, translations into EU languages undertaken by ECHA remains extremely important.

Malte-Matthias ZIMMER highlighted the importance of SMEunited being observer in the HelpNet, to have information and to be able to spread the knowledge to the member organisations as early as possible.

Participants welcomed SMEunited as a new observer in HelpNet, allowing them to gain the insights necessary to multiply the answers that helpdesks provide to companies' enquiries, and giving companies the best possible advice from the regulatory perspective.

5. Updates on the implementation of REACH and CLP

5.1 Updates from the European Commission

The updates[49] from the Commission were provided to participants as a document containing general updates on the implementation of the REACH and CLP regulations. One national helpdesk asked for clarifications on the Commission Implementing Regulation and Annex II to REACH, on which the Commission replied that:

- The Implementing Regulation regarding the application of certain registration and data-sharing provisions is foreseen to be voted in June, then adopted by the Commission, and published in autumn.
- A discussion and tentative vote on the revision of REACH Annex II is planned for the REACH Committee meeting in June 2019. As comments received on the cover note to the draft Annex II were discussed already in the REACH Committee meeting in February, additional discussions at the April REACH Committee meeting were not foreseen.

With reference to the Commission's replies, two Member States questioned if their comments on the draft Annex II have been taken into account for a possible discussion at the REACH Committee meeting in April 2019. The Secretariat will inform the Commission representative on this matter (HelpNet Steering Group, action point no. 3).

[49] Updates as of 22 February 2019.

As an update from the Commission is one of the most expected topics at the annual Steering Group meeting, HelpNet members would appreciate the Commission's representatives physical participation (or by videoconference) to future HelpNet events.

5.2 Updates from ECHA

Christian SCHULTHEISS (ECHA) presented a recent Board of Appeal (BoA) decision (Appeal A-005-2017), the General Court of the European Court of Justice (ECJ) judgment (T-837/16), and a brief update on the data-sharing work done in ECHA.

• Decision (Appeal A-005-2017)

Some years ago, REACH-IT was redesigned so that mandatory joint submission (JS) of a same substance became the only option technically available.

At the same time, ECHA sent letters to individual registrants (as a one-off exercise) of a substance identified by the same EC number, asking them to join an existing JS in accordance with Articles 11 and 19 of REACH.

This decision was challenged by one company who received the letter, one argument being that they do not have the same substance as the other registrants who used the same EC number as an identifier.

BoA found that the OSOR principle – according to Articles 11 and 19 – is not a legal basis for ECHA to issue decisions, with consequences as described in that contested decision. The BoA pointed out that incompliance should be examined by ECHA either under the compliance check process (dossier evaluation), or, if there is information lacking, under the completeness check process.

• ECJ judgment (T-837/16)

This judgement received quite some attention in the expert media. One Member State, supported by two other MSs and the European Parliament, challenged an authorisation granted by the Commission. In March 2019, the General Court of the ECJ issued a judgment annulling the Commission's decision granting an authorisation for some uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red. The Commission's decision was based on opinions made by ECHA's committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC).

The Court upheld the MS's plea that the Commission made an error during its examination of the absence of alternatives. The judgment indicates that the burden of proof is on the applicant for authorisation to show that there are no suitable alternatives for its uses, but it is the Commission, who is responsible for determining whether the conditions for authorisation are fulfilled. The Commission had, however, granted the authorisation without demonstrating the absence of suitable alternatives to the applicant. The absence of such detailed examination means that no authorisation should have been granted.

The decision can be still appealed by the Commission and the direct consequences[50] of the ECJ ruling on the authorisation decision for downstream users of lead chromate are unclear. (HelpNet Steering Group meeting, action point no. 4).

• Data-sharing disputes

With the reorganisation of ECHA, the REACH data-sharing disputes process is the responsibility of ECHA's Legal Affairs Unit. There were six data-sharing disputes submitted by 21 March 2019. As the phase-in period is over and Article 30, which contains the data-sharing process for pre-registered phase-in substances which are negotiated in the SIEFs, does not currently apply, ECHA handles the disputes using Article 27 of REACH as the legal basis.

The advantages for claimants are that the legal deadline for ECHA to handle these disputes is one month, and that a successful claimant can have access to both vertebrate and non-vertebrate data.

Another technical difference is that under Article 30, ECHA could make the assessment of the

[50] After the meeting, the question ID 16424 was posted in HelpEx by one national helpdesk (pending feedback from the Commission).

efforts made by the parties to reach an agreement and then grant a permission to refer – under Article 27, there is an additional condition, namely that a claimant has to provide a proof of payment of the share of the costs. If done so, the claimant receives permission to refer to the vertebrate and non-vertebrate data that is in the JS.

Should the Implementing Regulation on the operation of REACH after the expiry of the final registration deadline (see Section 2.2 of these minutes) come into force, Article 30 would potentially apply, under certain conditions, to some disputes until the end of the transitional period.

6. Updates on ECHA activities

6.1 Forum activities

Maciej BARANSKI (ECHA) provided an update on Forum activities, specifically on current and future Forum projects, reporting and other activities of interest to the HelpNet.

Completed Forum projects:

- REF-5 on extended safety data sheets (SDSs), exposure scenarios (ESs), risk management measures (RMMs) and operational conditions (OCs). The report is available on ECHA's website and presents the results of 898 inspections conducted in 29 EU and EEA countries, on 375 different substances, and 1 000 SDSs. The inspections were targeted to a) first level suppliers, b) suppliers of substances and mixtures, c) professional and industrial users, and even producers of articles. Conclusions of the inspections showed that systems are in place for the transfer and communication of safe use, and there is consistency between CSRs/extended SDSs. However, the quality of information communicated in the supply chain is low, most probably requiring the project focusing on the quality of the extended SDSs to be repeated.
- Pilot project on PIC51. National enforcement authorities from 13 Member States conducted 296 inspections. The customs authorities that have the remit to enforce PIC were also involved in this. This project was important as it was an opportunity to establish enforcement processes, gain more experience and put in place best practice to help future PIC enforcement actions. Results showed low levels of non-compliance: 10 % of exported chemicals did not have the required export notification, 4 % of chemicals were labelled incorrectly and 5 % of chemicals were missing the SDSs.

Ongoing Forum major projects:

- REF-6 – Classification and labelling of mixtures with a couple of modules on exemptions, CLH, liquid laundry detergent capsules (LLDCs) and biocidal products. The report is planned to be published by the end of 2019.
- REF-7 – Registration. In addition to registration duties, inspectors are also checking if companies update their registration dossiers. For registration of intermediates, strictly control conditions (SCCs) for intermediates are checked. The project is done in cooperation with customs authorities. Inspections started this year and will run until the end of 2019, with a report to be published in 2020.
- REF-8 – Online sales of chemicals focusing on restrictions and selected CLP provisions as well as some BPR duties. A manual is being prepared. Inspections are foreseen for 2020 and a report for 2021.
- BEF-1 – on treated articles under the BPR. Inspections are ongoing in 2019 and a report is expected in 2020.

In addition, the Forum has three ongoing smaller scale pilot projects 'Authorisation 3', 'Substances in articles', and 'Cooperation with customs'.

Maciej BARANSKI also informed participants about the work the Forum undertook to clarify the enforcement interfaces between REACH and OSH which would indicate to what extent the REACH

[51] Final report of the Forum pilot project on the control of PIC: https://echa.europa.eu/documents/10162/0/forum_project_on_control_of_pic_en.pdf/

information (e.g. exposure scenarios, safety data sheets) is used to comply with OSH legislation. This action is intended to support the Commission in conducting REACH Review Action 12(2), where the Commission is tasked with proposing steps to improve coordination of national enforcement authorities responsible for REACH and OSH legislation.

The subject of the 'Training for Trainers' scheduled in autumn 2019 is 'Control of online sales' (REACH/CLP/BPR). The Forum did not have enough trainers to accommodate breakout groups including the expected number of HelpNet representatives. If more trainers were not found, HelpNet members would be invited to follow the presentations by WebEx[52].

Regarding the 'Forum joint action on SDS quality', in which CEPE and Cefic are involved, Maciej BARANSKI informed that the Forum prepared a "Report on Improvement of quality of SDS", which will be made available to ASOs in May. Meetings with ASOs are foreseen to take place soon after to discuss potential actions by the ASOs. The first meeting with ASOs will take place in early summer and the second meeting is planned for late summer or autumn, providing sufficient time to prepare for the open session in November.

6.2 Communications activities

Johanna SALOMAA-VALKAMO (ECHA) presented ECHA's new communications strategy to participants, the new network bringing together communicators from ECHA, accredited stakeholders and Member State national authorities and the topical item of Poison Centres.

The new communications strategy aims to increase ECHA's visibility as a centre of knowledge on chemicals safety, serving a wide range of EU policies and global initiatives, for the benefit of citizens and the environment.

The new communications strategy integrates all areas of communications – external, internal and social media – and responds to challenges of increasingly complex communications landscape. To increase the visibility and use of ECHA's data and competences, ECHA is striving for the right tone of voice when communicating on defined priority topics to targeted key audiences.

To enable targeted messages and efficient outreach, as well as increased engagement of its key stakeholders, ECHA is working closely with all its partners at EU level – companies, industry associations, authorities and policy makers, general audiences, ECHA staff and ECHA community.

In terms of the general public as a target group, the Communications Unit is focusing more on activating Member State competent authorities, stakeholders and other partners as multipliers and amplifiers of trustworthy, accurate and understandable messages.

To reach out to audiences all over the EU, ECHA aims to reactivate the Communicators' network as an interactive, informal forum where Member States and ECHA can exchange ideas, best practice and information on various topics53 related to chemicals and communications.

The network will be launched in phases and operate mainly online. More intense cooperation would be expected towards the end of 2019 and beginning of 2020, and HelpNet members were invited to encourage specialised communicators from their organisations' to participate in the new Communicators' network.

Regarding poison centres, Johanna SALOMAA-VALKAMO informed participants of the existing communication and support material available on ECHA's website such as guidance, Q&As and videos. Some of them are already translated in all EU languages and more translations are planned in the future.

[52] Post meeting note: Forum did not find enough trainers so HelpNet colleagues will be invited to follow the training via WebEx.
[53] Potential topics: poison centre notification portal, tattoos, animal testing, microplastics, compliance checks, REACH post phase, substances for authorisation, nanomaterials, substitution of chemicals, etc.

7. Collaboration activities

7.1 EU-OSHA campaigns

Elke SCHNEIDER, Senior Project Manager at the European Agency of Safety and Health at Work (EU-OSHA) presented their activities on dangerous substances, focusing on the healthy workplaces campaigns[54] 2018-2019 and the roadmap on carcinogens.

EU-OSHA was established in 1994 and in 2019 is celebrating 25 years of working towards making Europe's workplaces safer, healthier and more productive.

Elke SCHNEIDER gave an overview of EU-OSHA activities – research, cooperation, participation in expert groups, supporting the European Commission – and future healthy workplaces campaigns. She introduced the EU-OSHA's beneficiaries, namely workers and employers with specific needs and higher levels of risks, with a special emphasis on those working in micro and small enterprises.

The 2018-19 campaign aims to raise awareness of the risks posed by dangerous substances in the workplace, promote a culture of risk prevention by promoting risk assessment, increase knowledge of the legislative framework that is already in place to protect workers, as well as highlighting policy developments. Supportive materials – campaign guide, info sheets, updated section, new articles, and an interactive e-tool - were developed to support the 2018-19 campaigns.

Elke SCHNEIDER highlighted the events to be held throughout 2019, including the ones organised with support from national focal points[55] and other campaign partners. Focal points[56] organise a wide range of campaign activities, support EU-OSHA's initiatives with information and feedback, and are using their networks to get governments and workers' and employers' representatives on board.

EU-OSHA is a signatory to the agreement committing to the EU Carcinogens Roadmap[57], aiming to reduce the number of cases of occupational cancer, raising awareness of the risks arising from exposures to carcinogens in the workplace and exchanging good practices.

Further discussions took place on the 'dangerous substances' terminology used in the context of occupational and chemical safety legislations and risk assessment tools.

Some participants expressed their appreciation regarding the number of health campaigns carried by such a small agency, appreciating the simple language used in communication, and the series of animations and the Napo[58] character supporting the EU-OSHA's Healthy Workplaces Campaigns and key campaign events.

Elke SCHNEIDER stressed that such education campaigns would be not possible without the cooperation with focal points and other agencies, including ECHA[59].

7.2 Visiting programme

Laura WALIN (ECHA) introduced participants to the **Visiting Programme**.

ECHA proposed to re-launch the visiting programme at the 13th Steering Group meeting in 2018, introduced in 2008 by ECHA's Executive Director. Since then, ECHA visited all the REACH and

[54] Healthy Workplaces Campaigns 2018-2019: https://healthy-workplaces.eu/
[55] Since 2018, 14 REACH/CLP national helpdesks are collaborating with EU-OSHA, as focal points, on healthy workplaces campaigns.
[56] National focal points: https://healthy-workplaces.eu/en/campaign-partners/national-focal-points
[57] Roadmap on carcinogens: https://osha.europa.eu/en/themes/dangerous-substances/roadmap-to-carcinogens
[58] Napo: https://osha.europa.eu/en/tools-and-publications/napo-safety-smile https://www.napofilm.net/en/using-napo/napo-for-teachers
[59] Memorandum of understanding between ECHA and EU-OSHA: https://echa.europa.eu/documents/10162/13606/mou_echa_osha_en.pdf/b6cc88e6-3d33-4b61-9846-1ba52081d8b2

CLP NHDs. Now, ECHA aims to get to know the work of the BPR helpdesks, and visit all three helpdesks of a given country in one go.

The visiting programme starting in 2019 marks a new era with new challenges – a different regulatory situation, novel types of customers, and new ways to support companies. Laura WALIN illustrated the objectives and the benefits of a helpdesk visit and the proposed draft agenda and questionnaire aiming to collect information about the targeted helpdesk and its needs.

The 2019 visits to NHDs, and from NHDs to ECHA, agreed as of mid-March were: Luxembourg (May), Hungary (August), Serbia (Q4), and Denmark (date to be confirmed) and the countries visiting[60] ECHA: Montenegro and Serbia (21 May).

Closing of the HelpNet Steering Group meeting

The Chair closed the 14th Steering Group meeting and invited the CLP and BPR members to the regulatory workshops of 4 April 2019.

[60] After the meeting, the Finnish Safety and Chemicals Agency (Tukes) confirmed their visit to ECHA on 21 May 2019.

CLP Workshop

Opening by the Chair

Outi TUNNELA (ECHA), the Chair, welcomed the CLP correspondents/alternates and observers participating to the CLP Workshop organised during the 13th HelpNet Steering Group meeting.

1 Joint session with BPR

The joint CLP and BPR session is covered under agenda points 1.1.1, 1.1.2 and 1.2.

1.1.1 ECHA implementation of CLP Annex VIII

Daniel SOMPOLSKI (ECHA) presented an update on regulatory matters related to Annex VIII to CLP, ECHA's IT tools being available allowing industry and authorities to comply with the legal obligations, the support material prepared by ECHA, and the cooperation with NHDs in reaching out to duty holders.

Regarding the recently published guidance document on Annex VIII[61], the open issue on the definition of duty holders and obligations of distributors was acknowledged. The guidance is planned to be revised soon, and for practical and financial reasons, the first version will not be translated. The representative of A.I.S.E. stressed that the translations of the first version of the guidance document would bring benefits to companies, and especially to SMEs who do not master the English language. It was explained that translations might not be finalised before an updated, stable version of the guidance would be made available.

In support to industry and Member State appointed bodies, ECHA has developed IT tools[62] to support preparing, submitting and receiving information on hazardous mixtures.

On the technicalities of the notification to ECHA's portal, Daniel SOMPOLSKI described the target audience for each of the available notification routes as follows:

- Cloud Services: the simplest one, with a wizard. Ideal for SMEs with a small portfolio.
- IUCLID: useful for those customers already knowledgeable on the notification tool.
- Poison Centre Notification (PCN) format: for advanced users, following a system-to-system approach, with no additional tools. Also, for the largest portfolios.

Daniel SOMPOLSKI then introduced then the support material under preparation or already available on the Poison Centres website[63]. The web section contains a questions and answers section[64], guidance, publications[65] (guides and manuals to the UFI Generator tool and the PCN format, as well as to the European product categorisation system (EuPCS)) to help companies understand and comply with their obligations relating to placing hazardous mixtures on the market.

1.1.2 NHDs questions on Annex VIII

An JAMERS (European Commission, DG GROW) explained that the obligations of distributors had been discussed in CARACAL-28. While the commenting period was open, the Commission was not in favour of changing their views. She acknowledged that not requiring distributors to notify would lead to a loss of information. In this context, there are three possibilities:

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[61] Guidance on harmonised information relating to health emergency response Annex VIII to CLP: https://echa.europa.eu/documents/10162/13643/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11

[62] Tools: https://poisoncentres.echa.europa.eu/tools

[63] Poison Centres: https://poisoncentres.echa.europa.eu/home

[64] Questions & answers: https://poisoncentres.echa.europa.eu/questions-and-answers

[65] Publications: https://poisoncentres.echa.europa.eu/publications

- First, the distributor, in complying with Article 4(10) of CLP, can inform the supplier, who then notifies.
- The second possibility would be that the distributor notifies and uses the existing unique formula identifier (UFI) of the mixture, as long as this one has been notified.
- Third, the distributor could notify based on the information they get in the SDS. This option would be the one for re-branders when the UFI has not been notified in that specific Member State, or the distributor does not receive additional information from its own supplier beyond the SDS. The loss of information (especially on full composition) was acknowledged in this case.

It was pointed out that if an industrial mixture ends up in a consumer product, then it is considered to be for consumer use and should be notified by the first deadline.

The participants were also informed about the workability study that was still on going until June, and the results should determine if further amendments of Annex VIII are necessary.

It remained unclear whether it should be recommended to add the UFI on a product already now, if the notification applicability date for the product is still far away. The handling of mixtures not included in the European Product Categorisation system (EuPCS) (such as food additives) was also not clear.

From industry's side, there was a need for guidance and translated material. Moreover, having the UFI on the label or the packaging is a costly and time-consuming decision. Therefore, a progressive implementation of the transitional period would be appreciated.

It was clarified that the discussion on UFI placement seems to indicate that the UFI could also be placed directly on the packaging, close to the product identifier information on the label. Article 25(7) makes this link clear. There would be no need to amend Annex VIII. However, the amendment of Annex II to REACH considers the UFI as a 'product identifier', requiring its inclusion in Section 1.1. of the SDS.

The concern that Article 45 does not explicitly refer to Annex VIII was expressed, as this can affect enforcement. Article 45(4) does provide the basis for any enforcement of CLP. As this topic was outside the remit of HelpNet, ECHA proposed to raise the question in the Forum.

1.2 Labelling of treated articles

Janice ROBINSON (CEPE) gave a presentation on the challenges that industry experiences when complying with both CLP and BPR labelling requirements in relation to paints, printing inks and artists' colours containing biocides. It was highlighted that companies face difficulties to simultaneously fulfil labelling requirements for treated articles under CLP and Article 58(3) of the BPR. Particularly, it was mentioned that:

- A large amount of information can create space issues when it comes to the labelling of small packages. Given space constraints, it is important to avoid repetition of the substance name and use abbreviations, if possible (both CLP and BPR require the substance names to be included in the label).
- It is difficult to align labelling requirements when different regulatory deadlines/changes apply to different regulatory processes under CLP and BPR.

  CLP labelling requirements are prescriptive and dependent on the concentration threshold, whereas BPR labelling requirements are free text and not dependent on the concentration.
- It is difficult to interpret labelling rules under Article 58(3) of the BPR, as a result, different MSs interpret requirements differently.

To help companies comply with both regulations, CEPE has developed guidance documents containing recommendations that provide practical examples. Recommendations cover general principles on how to name substances and how to combine BPR and CLP labelling requirements. Among participants, it was acknowledged that there is a need to align labelling requirements between BPR and CLP. Participants were invited to provide feedback on CEPE's guidance on

labelling of treated articles[66] (CLP Workshop, action point no. 1).

During the discussion, it was mentioned that Member States should adopt a more user-friendly interpretation of the legislation and work together to harmonise labelling requirements, aiming at simplifying requirements for users and avoiding inconsistencies, or repetitions. Finally, it was mentioned that when developing labelling FAQs, it is necessary to take into account both CLP and BPR (e.g. FAQ for detergents).

2. Break-out groups

CLP participants discussed the classification and labelling of mixtures in multi-compartment soluble packaging, the aquatic hazard classification of mixtures under CLP, and the possibilities of digitalisation of product labels.

2.1 Classification and labelling of mixtures in multi-compartment soluble packaging

The discussion was based on earlier questions in HelpEx, regarding how products should be classified and labelled, when they contain several mixtures in individual compartments of a soluble packaging. The discussion also considered whether the small packaging exemption for volumes below 25 ml should apply to the whole product, or the individual compartments.

The main thoughts arising from the discussions were:

- When the compartments contain different mixtures, the classification of each mixture should be given on the outer packaging. This principle follows the approach agreed for the labelling of kits in the UN GHS. The mixtures should not be classified as one single mixture, as this does not reflect the mixtures as they are placed on the market and thus such an approach does not have a legal justification.
- Another suggestion was to indicate a 'worst case scenario', giving the most severe hazards of the mixtures. This, however, does not have a legal basis or clear guidelines.
- Each mixture should be identified with its own UFI, linked to the others for the product in the Poison Centre Notification.
- The labelling of the individual compartments of the soluble packaging is not possible in such a way that the text would be legible. Also, having too much information on the packaging is not recommendable, as keeping the product in the hand too long would be highly counterproductive: the packaging would dissolve before the text has been read. The best option would be to print only the pictograms on the soluble packaging, to highlight to the reader that the product is hazardous and that they should remember to re-close the outer packaging carefully.
- Because these products may only be sold in packaging that conforms to the requirements for child-proofing, the placing on the market of individual soluble 'pods' (or sachets) should be clearly forbidden. These are sometimes sold as 'appetisers' and given as samples.
- The labelling of the outer packaging may sometimes be challenging, especially when several languages are required. The possibilities of reducing duplicate information should be seriously investigated.
- The main task would be to continue and enhance consumer awareness-raising. However, the last resort would be to propose a restriction.

2.2 Mixtures and Aquatic Hazard classification under CLP

Simon UPHILL (ECHA) presented 'Mixtures and Aquatic Hazard classification under CLP'.

The discussion concentrated on two topics:

[66] CEPE guidance 'Labelling of Treated Articles' uploaded on S-CIRCABC after the meeting and available at: http://www.cepe.org/wp-content/uploads/2018/01/BPR-revised-guidance-Art-583-v3-Nov-16.pdf

- Formulators are the main actors in the supply chain facing the need to classify mixtures. However, they tend to lack knowledge and expertise for this. In addition, they lack reliable information, which for substances is held by the manufacturers/importers and is documented in a registration dossier. There are a number of software solutions with unknown reliability used to create SDSs and classify mixtures.

- A guidance update would be needed. The document would benefit from clearer, closer to life examples (mixtures with many substances), and translation into all EU official languages. A more interactive format would be appreciated, similar to the mixture classification web pages. A further development could be a manual focused on classification, with visual decision trees. To correct specific issues, such as the example discussed during the breakout group, a quick way could be the publication of a Q&A.

Another aspect discussed was the preference for the summation method, and to which extent ECHA can promote it even more.

2.3 Opportunities on digitalisation of CLP hazard information

Roberto SCAZZOLA (A.I.S.E.) presented the opportunities on digitalisation of CLP hazard information.

The group discussed the results of consumer research studies that show that the current implementation of the GHS/CLP labelling of chemicals is not fully effective at conveying safe use and hazard information to the general public: labels are overloaded and unattractive, and text is often too small to read (see also the minutes of HelpNet 13).

Digitalisation offers opportunities for addressing these challenges: language and adaptable font size to meet users' needs and preferences, customised search options for keywords could allow swift identification of the key information (e.g. presence of a specific sensitising substance).

Information such as safe use instructions and sustainable tips could also be easily accommodated digitally, updates and new information could also be provided timely through electronic labels. In addition, digitalisation offers a viable option for complementing the limited information given on the physical label of very small packaging and for addressing the issue of online purchases made in different countries (e.g. different languages).

In terms of challenges, it was recognised that backup solutions would be needed (telephone line, remote reader, etc.) and that even if digital labels were accepted, a paper label containing the key information would always be needed.

Concerns were expressed with regard to data protection when accessing the digital information. The selection of the appropriate information that could be displayed only digitally was also of concern.

Overall, HelpNet members welcomed the proposal on digitalisation of hazard information on chemicals and encouraged further discussions at UN GHS and EU level on this topic.

3. Updates from ECHA and CARACAL

3.1 Forum projects

Maciej BARANSKI (ECHA) gave a presentation on the Forum's current activities that are related to CLP. The project on cooperation with customs includes a check of labelling in case of a physical check of the goods. If the package is leaking or there is no transport labelling or CLP label on the packaging of hazardous substance, then the customs will call CLP inspectors to check. It can be the case that a customs inspector calls their CLP colleagues for the physical inspections, where the REACH/CLP inspectors would control all relevant CLP/REACH duties covered by the project in one go.

Maciej BARANSKI clarified that the manual of conclusions is accessible to HelpNet correspondents (not observers) in S-CIRCABC. The observers can consult the published minutes of the Forum

meetings. Following a request from one of the observers, Maciej BARANSKI offered to inquire with the Forum whether it would be willing to prepare some public version of the manual of conclusions (CLP workshop, action point no. 2).

3.2 Topics of interest from CARACAL-29

The Chair updated the participants on certain topics under discussion at CARACAL-29.

As the discussion platform for C&L notifications did not work and has been removed, it has been suggested that the names of the notifiers should be published on ECHA's website, to enable communication between notifiers. Most MSCAs supported the idea of publishing the names of C&L notifiers. The paper explaining this action was open for comments until the end of April.

Little progress has been made on other topics. Regarding aerosol classification, the results from the written comments after CARACAL are still expected (commenting deadline was 16 April). On additivity, an oral update was presented at the meeting, with the possibility to comment after the CARACAL meeting.

4. Topics proposed by HelpNet

4.1 HelpEx 16304: small packaging, CLP Article 29

The Chair presented a question from HelpEx where the interpretation of CLP Article 29, paragraphs 1 and 2, has been discussed. The current legal text is written in a way that it requires the conditions of 29(1) to be fulfilled before 29(2) can be considered. The usefulness of Article 29(2) was questioned, as there seemed to be an understanding that paragraph 1 would always apply.

In the discussion, it was considered that point 1.5 of Annex I was ultimately clearer than Article 29. To some extent, it seems the current wording of CLP is forcing an outer packaging to be added, which in a wider scope is not sustainable, economically or environmentally.

As some participants emphasised, this was not the original intention when the provision was taken over from the previous legislation. Some participants considered that the discussion was too theoretical and industry should bring real examples to help properly understand the issue, as well as options to solve it.

ECHA said that they would check the final view of the legal unit on whether an official request for clarification would be sent to the Commission. This was clarified after the meeting, and from ECHA's point of view, the legal text is clear and there is no need to make a formal consultation to the Commission. However, an informal request was sent to them, asking them to clarify what really was the intention of the legislator and whether a change to the wording would actually be needed to reflect the real intention.

4.2 Practical labelling issues

The following issues were brought up for discussion:

1. A question was raised about the placing of pictograms on fold-out labels. The understanding is that for fold-out labels, the part firmly attached to the bottle needs to include certain information (as required in point 1.5 of Annex I to CLP). This includes the pictograms. It was questioned whether this is mandatory, or if these elements can be on other pages of the fold-out. ECHA clarified that the *Guidance on Labelling and Packaging* already tackles this issue, and the agreed recommendation is that these elements should be placed on both the top page and the page attached to the immediate packaging.

2. Regarding the hazard statement EUH202, it was concluded that it is mandatory to have it on the immediate inner packaging. The question was related to nail and lash glues, where there is an interface with cosmetics. As it was not clear which regulation prevails regarding these products, the question was informally addressed to the Commission.

3. There was concern about the labelling of fuels for cars and heating systems, covered by Article 29(3), and their possible inclusion in Part 5 of Annex II. There are, at present, different practices in different Member States regarding the labelling of these products, and these are not necessarily based on CLP, but other legal requirements. As the issue had already been discussed in the CASG-LP in 2015, the COM was again asked to check if the addition of fuels in Annex II could now be proposed.

Closing of the CLP Workshop

The Chair closed the session by reminding participants about the ECHA Conference to be held in Helsinki on 21-22 May 2019. This is the new name for the ECHA Stakeholders' Day. The Chair asked the NHDs to forward the announcement. In the programme, there will be a training session on Poison Centres notification.

BPR Workshop

Opening by the Chair

1. Joint session BPR and CLP

The Chair opened the session, explaining that the first part was combining the BPR and the CLP workshops, considering the overlap of the topics presented. Should the participants of both workshops find this approach useful, it can be repeated in future events.

The action points of the previous BPR and CLP workshops would all be completed for the BPR side with Agenda point 3.2 'HelpNet - handling scope related BPR questions'. For the CLP side, all were already completed.

The agenda for the day was approved.

Agenda points 1.1.1, 1.1.2 and 1.2 are summarised under the CLP Workshop.

1.3 Member States' experience and challenges in the CLH process

Due to time constraints this agenda item was not addressed in the joint session.

2. Updates from the European Commission and ECHA

2.1 Updates from the European Commission

Mario NAGTZAAM and **Ligia NEGULICI** (European Commission, DG SANTE) provided an update on several BPR topics:

- Review Programme Regulation

It was highlighted that only a third of the work programme has been concluded and that there are significant delays with the evaluation of the rest of the substances included in the Review Programme. Member States, stakeholder representatives and ECHA have been discussing concrete actions for improving the situation and accelerating the evaluation of active substances. Discussions are still on-going.

- Renewals of active substance approvals

It was mentioned that applications for active substance renewals are expected to increase every year. It was highlighted that Member States should monitor the situation of granted biocidal product authorisations containing active substances for which renewal applications are expected to be submitted. It was indicated that guidance on the assessment of renewal applications is under development.

- Endocrine disruptor assessment

Implementing or delegated acts related to the endocrine disruptor (ED) assessment are expected to be developed in the near future (it is likely that a draft delegated act will be presented at the competent authorities meeting in May). A draft Coordination Group (CG) document will provide guidance on the ED assessment of non-active substances. A review of three active substances (iodine, PVP iodine, zineb) that will be evaluated against the ED criteria is expected to be triggered by the Commission in the second half of the year.

- *In situ* biocidal products

It was clarified that discussions related to in situ biocidal products are still ongoing and the final CA paper will provide guidance related to data requirements. In addition, the paper will explain how the biocidal product family concept can be applied to in situ biocidal products, it will indicate the information to be included in the specific product characteristics and will provide some case-type examples of in situ products.

- Biocidal Products Family

It was acknowledged that further criteria for the assessment of 'similar uses', 'similar composition with specified variations' and 'similar levels of risk and efficacy' need to be developed and a Working Party within the Coordination Group is engaged in elucidating such criteria. An updated CA document related to biocidal products family is expected to be discussed in the May CA meeting.

- Union authorisations

Based on a general overview of UAs granted so far, it was noted that the number of applications received was significantly above the estimates, if same biocidal products of Union authorisations are taken into account. The main product types covered by UAs are represented by disinfectants and a combination of disinfectants with preservatives. It was mentioned that the distribution of Union authorisation applications among CAs has been somewhat unbalanced (58 % to NL eCA). Difficulties to evaluate applications derive not only from the unbalanced distribution, but also from the fact that dossiers mainly correspond to BPFs and cover multiple product types. Finally, it was highlighted that there is a need to better promote pre-submission meetings to decrease the number of incomplete dossiers.

- BPR and innovation

It was highlighted that the BPR stimulates innovation and safe use of chemicals. In particular, it stimulates research and development (Article 56), facilitates earlier access to the market of certain biocidal products (Article 55 – provisional authorisation), stimulates new active substances (longer data protection period compared to existing active substances – 15 versus 10 years, respectively), and drives the substitution of substances of concern with substances presenting an overall lower risk (Articles 5, 10 and 23). In addition, a number of ongoing EU innovation programmes aim at raising awareness on safer chemicals.

- Article 65 reporting

Article 65 of the BPR imposes reporting duties for both Member States and the Commission. It was pointed out that the next deadline for reporting on the implementation of the BPR corresponds to June 2020 and that a two-stage approach on how to report has been agreed in the CA document 'CA-Jan18-Doc.7.5.a'. The reporting template still needs to be refined, hence, further discussions will follow at the end of the year, or beginning of next year.

After the presentation, Mario NAGTZAAM provided clarification on topics for which Member States had shown interest. Particularly, he clarified that:

- Detailed information on Annex I management is available in the CA paper[67]
- Article 93 transitional measures apply – the legislation is clear on this point.
- Article 95 does not apply to treated articles, but only to active substances and biocidal products.
- The labelling of in situ biocidal products will be addressed in the upcoming CA paper related to in situ products.

During the discussion it was mentioned that the delay in evaluating the substances included in the Review Programme represents an issue which needs to be tackled. One Member State mentioned that the Review Programme has been very ambitious from the start, given that it is complex to evaluate substances for 22 different product types. She added that the evaluation of existing active substances will, in the near future, become even more difficult given the loss of UK experts, due to Brexit, and the evaluation of the upcoming renewal dossiers. The Chair asked whether the deadline for completing the evaluation of the RP substances will be postponed beyond 2024. The presenter indicated that, given the significant delay, this might be the case.

[67] CA-Nov18-Doc.5.3 - Final - Management of Annex I to BPR.doc.

Finally, Mario NAGTZAAM provided clarification to a question raised by one NHD at the HelpNet 13 related to the Annex I inclusion of in situ generated nitrogen. He explained that 'Nitrogen', which is already included in Annex I, does not cover the *in situ* generated nitrogen and that a separate Annex I entry would probably be required to cover the in situ substance. He indicated that upcoming discussions in the May CA meeting will clarify the way forward.

2.2 Updates from the Forum BPR Subgroup

Nicola TECCE (ECHA) presented an update on the enforcement activities related to the BPR, providing an overview of the state-of-play of the BPRS and its Working Group's (WG) activities.

The BPRS-7 plenary took place on 22 March and the core topic of the meeting was the first enforcement project on treated articles (BEF-1). The operational phase of this project was kicked off in January 2019, and the inspectors are already making inspection visits to monitor and enforce treated articles. The manual and questionnaire for inspections were adopted and translated in the national languages during the preparatory phase of the project in 2018.

While the main focus of the project is consumer products, professional uses are also covered. The key aspects that will be analysed during the project are the labelling provisions, and the potential presence of non-approved substances on the EU market. The inspections will last until the end of 2019 and a report summarising and analysing all the relevant input received will be produced at the beginning of 2020.

A new BPR enforcement project, on the online sale of biocidal products (REF-8) was agreed during the last plenary of the BPRS. Both products authorised and products placed on the market under transitional provisions will be under the scope of the project. The operational phase of the project will be kicked off in January 2020.

An update from the other BPRS WGs was delivered. The Working Group on the 'Portal dashboard for national enforcement authorities on BPR' aims to develop a software with information on biocidal products better tailored to the needs of inspectors.

The work on the REF-6 project, including on the labelling and classification of biocidal products, is currently in its reporting phase and the final report is expected to be finalised by Q4 of 2019.

The audience was informed that an open session with stakeholders took place in November 2018 in Brussels. The European Association of Chemical Distributors (FECC) and the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) presented topics relevant for the national enforcement authorities (NEAs) and Commission, respectively on the storage tanks for active substances and the labelling of treated articles.

Concerning the collaboration with other bodies, during the last plenary the BPRS decided to work together with ECHA's Biocidal Product Committee (BPC). The BPRS will provide its expertise on the enforceability of proposed risk mitigation measures, in the context of substance approvals and Union authorisation. A pilot project will be soon launched and if successful, ad hoc consultations from the BPRS will be triggered by the BPC, when needed.

The highlights from the first 'Training for national inspectors on treated articles' were briefly presented. In October 2019, there will be a second event focusing on online sales. The NHDs will be invited to follow the event remotely.

The speaker also debriefed the plenary on the work related to practical issues on enforcement, which are essentially questions from inspectors. The NEAs are currently working on several aspects of the legislation to get clarity and a consistent interpretation. The conclusion of the first practical issue was adopted and included in the manual of decisions and focuses on treated articles. The Secretariat will share the document with the BPR NHDs for their information and use, subject to the agreement of the BPRS.

Finally, Nicola TECCE mentioned that in June 2019 there will be a workshop on best practice and common problems faced by national inspectors during the enforcement of treated articles in the framework of the BEF-1. This will be a good opportunity to discuss and agree on harmonised views among the NEAs.

3. Working together

3.1 UK's withdrawal from the EU - facts and figures

Valerio SPINOSI (ECHA) presented facts and figures on the impact that the UK's withdrawal from the EU will have on ongoing BPR processes.

The first part of the presentation referred to active substance-related processes. Valerio SPINOSI clarified that whenever the evaluating competent authority (eCA) for an active substance evaluation process (AS-EVA) was the UK, the Commission had requested to switch to an EU-27/EEA eCA. All review programme substances have been appointed to a new eCA. This had to be done promptly since in the amended Review Programme Regulation, the deadline to perform the change was 29 March 2019. When it comes to AS-EVA or renewal procedures for new active substances, the actual deadline to perform the switch will be the date of the UK's withdrawal from the EU.

The second part of the presentation concerned product-related processes. The ongoing national authorisation cases based only in the UK will be terminated following the date of withdrawal.

For ongoing mutual recognition in parallel procedures (NA-MRP), when the UK is a reference Member State, a change to a concerned Member State should be made. The Commission agreed that, when a volunteer could be found, the evaluation could be shifted. However, if this is not the case, the concerned Member States will have the possibility to finalise the authorisation only when there is an agreed summary of biocidal product characteristics (SPC). For all other cases (three at the time of the presentation), there might be a need to terminate them following the withdrawal of the UK; the situation is being monitored.

Following recent developments from the Commission, it was mentioned that a similar approach would be adopted for ongoing mutual recognitions in sequence (NA-MRS). Provided that an SPC is agreed by the concerned Member States, they will also have the possibility to finalise the authorisation after the date of withdrawal.

Renewals of authorisation will need to be processed by an EU-27/EEA eCA. Ongoing cases where the reference Member State is the UK will be terminated as of the withdrawal date. An application would need to be sent to one of the concerned Member States. The same applies to change applications.

For simplified authorisations, all assets (four at the time of the presentation) where the reference authorisation was based in the UK will be terminated. Similarly, all notified assets linked to those four reference authorisations will be terminated.

During the Q&A session, some topics discussed regarded the flexibility of the IT systems. It was clarified that the assets based in the EU-27/EEA would normally not be affected directly. Following the date of withdrawal, it will be up to the competent authorities to address potential enforcement issues.

Another point discussed regarded the need to change the reference Member State of authorisation assets granted in an EU-27/EEA country following a mutual recognition procedure where the UK acted as a reference Member State. It was mentioned that in case ofmutual recognitions in parallel (MRPs) this change would be implemented automatically, while in the case of a mutual recognition in sequence (MRS) this would normally happen when a change/renewal is needed. While, in principle, companies could request the change to be done before the actual need arises, the issue might need to be brought to the Commission, as many simultaneous requests could have workload implications.

3.2 HelpNet - handling scope related BPR questions

Anna-Liisa PIKKARAINEN (ECHA) explained that during the HelpNet13 workshop on biocides in October 2018, the HelpNet Secretariat undertook the task to propose a clear and linear process to handle scope-related questions. She explained that the purpose of this project was to improve the transparency and efficiency of the procedure.

The main actors involved in the process are the national BPR helpdesks, the European Commission and the ECHA Secretariat. It was highlighted that ECHA's role will be related to the tool administration and that ECHA won't participate actively in discussions regarding the scope of the BPR.

As a first step, the streamlined process will involve bringing topics of interest at the HelpEx level. This will allow Member State views to be mapped and best practice to be shared. If necessary, complex topics identified during the first step can be discussed during the HelpNet meetings as a second step. Finally, if no consensus can be reached from the HelpNet discussions, the issues can be brought to the Commission (third step).

During the Q&A session, positive feedback on the procedure was received. The importance of having representatives from the Commission in the discussions was mentioned by the participants. ECHA agreed that the outcome of discussions made during WebEx/HelpNet meetings will be shared with national helpdesks.

3.3 BPR dissemination portal

Anita RYNKÄNEN (ECHA) gave a presentation on the improved BPR dissemination portal and reported on the results of the survey where national BPR helpdesks were asked to give feedback on navigation, new features and the user friendliness of the new web pages.

It was noted that the new pages launched in November 2018 aimed to:

- Achieve a greater compliance with Article 67 of the BPR, related to dissemination (e.g. publication of documents such as SPCs and PARs);
- Centralise access to biocides data;
- Introduce new functionalities that facilitate the navigation through the portal (extended search functionalities, visual elements, comparison tool).

Sixteen BPR national helpdesks provided feedback on the new dissemination pages. In general, the feedback was quite positive. It was mentioned that access to information has significantly increased, the search and filter features are adequate and easy to use and that the changes have increased user-friendliness. However, some suggestions for improvement were also highlighted:

- More details on the assessment steps of active substances should be provided;
- Visual elements could be further improved;
- Notifications should be launched if there are changes related to active substances/biocidal products.

Valerio SPINOSI kindly reminded participants not to forget to classify the documents correctly as 'restricted' if they are not meant to be disseminated, emphasising that it is important to carefully protect confidential information as well. In case of doubts, he suggested to contact ECHA through the ECHA contact form[68] for assistance.

3.4 Update on the active substance workshop programme

Laura RUGGERI (ECHA) presented an update on a workshop on the evaluation of active substances that took place on 12-13 February 2019.

After 15 years of the Review Programme, only one-third of the active substance/product type combinations have been evaluated. As a result of this, there are currently several unregulated

[68] Contact forms: https://echa.europa.eu/contact

products on the EU market and there is no level playing field for companies in the biocides sector. To tackle these issues, a workshop, with representatives from 23 MSCAs, four ASOs and the Commission, was organised.

While some positive aspects were highlighted, such as the progress made from the previous workshop in 2015, and the fact that the resources available to the authorities have increased, there is still a lot of work to do. The main problems that were identified were: despite the increase, a lack of sufficient resources and due to the increased workload, unclear priorities, incomplete dossiers, lack of pragmatic solutions and the complexity of the evaluation procedure.

There is no single solution to these different issues. Some ways to reduce the complexity of the evaluation procedures could be to focus on what really matters, to group similar active substances and to facilitate access to guidance documents.

ECHA could play a role through coordination and supporting activities, for example, through the activities of dossier managers and national contact points dedicated to each Member State. ECHA could possibly support the eCAs by taking over some tasks of the dossiers and providing guidance in relation to grouping and the interface between the BPR and CLP.

The first follow-up to the workshop will be to contact eCAs and ask them in which tasks ECHA could support or take over on high priority dossiers (Backlog and Review Programme). Concrete follow-up actions and proposals will be proposed at the May CA meeting and a summary report on the workshop will be drafted.

During the Q&A sessions, some participants mentioned that the fact that CLH dossiers do not make use of IUCLID formats creates difficulties as CAs have to enter the data manually. It was commented that ECHA is aware of this point and working to improve the situation.

4. Break-out groups

4.1 Disinfectants - identification of the relevant PT

Solveig AAMODT (Norwegian Biocides helpdesk) introduced the topic of the breakout group and led the discussion. The starting point was the observation that several members had raised scope-related questions on disinfectants in the HelpEx platform covering different point of views.

The topic – 'Disinfectants – identification of the relevant product type – was selected for the breakout group discussion. Before the BPR workshop, participants had the opportunity to become familiar with the relevant issues raised for discussion through information provided by Solveig AAMODT.

1. **Distinction between main group 1 and 2 of BPR Annex V**

The clarity of the distinction between disinfectants and preservatives – which are two of four main groups of biocidal product types – was considered, on a general level, somehow clear. However, for example PT2, with the description 'disinfectants and algaecides not intended for direct application to human or animals', can be confusing because of its wide scope. Identifying the intention of a biocidal product and comparing this with the intention or scope of the product type (i.e. reading the use description of the biocidal product and the product type definitions in BPR Annex V carefully) is helpful in all cases of allocating a biocidal product to a product type. However, the intention or scope of PT2 is not so clear, since it can contain a wide variety of products where the level of efficacy needed covers a wide range. Furthermore, main group 2 (preservatives) can contain both curative and preventative products (CA-Sept15-Doc.8.3[69]) – so this can also not be used as an absolute distinction between the main groups.

Therefore, some clarification from the Commission could be useful. It was highlighted that, in addition to the definition of the product type and available efficacy-related guidance there may also be a need to consult the efficacy experts to allocate the products to the relevant main group. In some cases, PT2 is simply selected as a 'last resort', if it is difficult to find a suitable product-type.

[69] CA-Sept15-Doc.8.3 - Curative use of preservatives.doc

2. PT2 or PT3?

The discussion on identifying the right product type within the main group disinfectants, focused mainly on PTs 2 and 3 – 'disinfectants and algaecides not intended for direct application to human or animals', and 'veterinary hygiene', respectively.

There was no consensus on the borderline between PT2 and PT3. There was some agreement that PT2 is mainly meant to benefit human health, however, there was confusion regarding water disinfection. Are the algaecides for aquariums and other waters included in the PT2 definition meant to benefit humans (to e.g. maintain a pretty aquarium with clear water and glass) or to maintain healthy animal (fish) populations). For the latter, some participants were of the opinion that water disinfection for animal hygiene should be a PT3 use, while others argued that it was a PT2 use because of the mention of aquariums and other waters in the PT2 definition. There were also differing opinions on whether aquariums could be interpreted in a wide sense to cover aquaculture facilities. It was also discussed whether it could it relevant to consider PT5 (disinfectants for drinking water) in some of these cases.

The scope of PT3 is veterinary hygiene. This is clear from the definition, unlike for PT2 (where both humans and animals are mentioned in the definition). Disinfectants for animal premises usually belong to PT3. Concerning disinfectants for animal housing on land and in water, there was some agreement that both air and water should be considered animal surroundings and hence PT3 would seem relevant, but again there was confusion regarding water disinfection (aquariums, fish). Also, air and water disinfection might not be directly comparable in all cases. It was further mentioned that borderline cases between PT3 and veterinary medicinal products (VMPs), or between PT3 and other PTs, for example PT18 ('insecticides, acaricides and products to control other arthropods') are common. As detailed as possible description of the use of the product is always useful in these kind of cases.

Concerning the likelihood of residues from the use of disinfectants, it was agreed that this is under consideration during the evaluation phase and should not be a criterion for product type allocation.

Conclusions

A need was identified for discussing the scope and intention of PT2 with the Commission. From the first topic, a need for clarification was identified for the borderline between PT2 and preservatives (main group 2).

4.2 Identification of the mode of action

Renato CABELLA (Italian Ministry of Health) introduced the HelpEx questions 14501 (UK), 14901 (DE) and 16003 (IT) to the participants and chaired the discussion. These questions were on the identification of a biocidal mode of action.

HelpEx 14501 consisted of a product that facilitates the removal of algae. While some similarities with the Söll judgment[70] were mentioned, it was argued that more information would be necessary to rule out that the product is not a detergent.

HelpEx 6003 regarded an active substance consisting of a matrix of inorganic trace elements. Based on the information provided by the applicant, the matrix would inhibit a biofilm formation following an alteration of the electric field of the matrix. The participants agreed that this product would fall within the scope of the BPR (either as a biocidal product or as a treated article), considering that a chemical reaction induces the biocidal property of the product.

HelpEx 14901 regarded an alkane water emulsion that, through the creation of a thin film on parasites, causes the drowning and drying of larvae. Considering that the participants deliberated that there is no chemical reaction that triggers the biocidal function, this should not be considered as a biocidal product.

[70] Judgment of the Court: http://curia.europa.eu/juris/document/document.jsf?docid=119906&mode=req&pageIndex=1&dir=&occ=first&part=1&text=&doclang=EN&cid=1690036

A take-home message from this breakout group was that often detailed information is required to assess the mode of action. More guidance should be given to applicants to clearly indicate which information they need to provide. This could facilitate the task of decision-makers.

Secondly, since often mechanisms of action involve many different steps, the evaluation should also cover the intermediate steps and not focus, for example, only on the final step of a given mechanism.

Finally, the participants highlighted the importance of considering the claims made by the suppliers when deciding on the nature of a product.

Closing of the BPR Workshop

The Chair thanked all participants for their active and valuable contributions to the workshop and closed the event.

Annex I - List of participants

Members of HelpNet

Country	Members of the HelpNet		REACH Workshop	HelpNet Steering Group meeting	CLP Workshop	BPR Workshop
	First Name	Last Name	(2/04)	(3/04)	(4/04)	(4/04)
Austria	Peter	SCHINDLER		√		√
Austria	Barbara	WETZER	√	√	√	
Belgium	Kristof	CLAES			√	
Belgium	Daphné	HOYAUX	√	√		
Belgium	Ali	QADARI				√
Bulgaria	Elena	ZIDAROVA	√	√	√	
Croatia	Romana	GRIZELJ	√	√		
Croatia	Silva	KAJIC		√		√
Croatia	Zdravko	LOVRIĆ		√	√	
Cyprus	Maria	ORPHANOU	√	√	√	
Cyprus	Maria	PALEOMYLITOU		√	√	
Czech Republic	Jan	KOLAR		√		
Czech Republic	Jarmila	SLADKOVA	√	√		
Denmark	Lone	KÆRGAARD		√		√
Denmark	Iryna	MARCUSLUND		√		√
Denmark	Maria	THESTRUP JENSEN	√	√		
Estonia	Anna	AMELKINA	√	√		
Estonia	Aigi	LAHE		√	√	
Estonia	Riina	LAHNE		√		√
Finland	Hannu	MATTILA		√		√
Finland	Jussi	OLLIKKA		√	√	
Finland	Leeni	TOLSA		√	√	
Finland	Sari	TUHKUNEN		√		
Finland	Pauli	KÄRKKÄINEN	√	√		
France	Gaëlle	DUFFORT	√	√	√	
France	Nathalie	HAYAUD	√	√	√	
Germany	Irina	JANSEN		√		√
Germany	Anja	KNIETSCH		√	√	
Germany	Suzanne	WIANDT	√	√		
Greece	Dimitra	GKILPATHI		√		√
Greece	Panagiota	SKAFIDA	√	√	√	
Hungary	Boglárka	DURUCSKÓ		√	√	
Hungary	Nikoletta	MAROSVÖLGYI	√	√		
Hungary	Emese	SZÁNTÓ		√		√
Ireland	Caroline	WALSH	√	√	√	
Ireland	Patricia	MC GUIRE		√		√
Italy	Maria	ALESSANDRELLI		√	√	
Italy	Francesca	CARFÌ	√	√		
Latvia	Kristīne	KRAFTE		√		√
Latvia	Amanda	OZOLA	√	√	√	
Lithuania	Agnė	JANONYTĖ		√	√	
Lithuania	Natalja	UMBRASIENE		√		√
Lithuania	Beata	VOLUJEVIČ	√	√		

Country	Members of HelpNet		REACH Workshop	HelpNet Steering Group meeting	CLP Workshop	BPR Workshop
	First Name	Last Name	(2/04)	(3/04)	(4/04)	(4/04)
Luxembourg	Laurene	CHOCHOIS	√	√		
Luxembourg	Oona	FREUDENTHAL		√	√	
Malta	Nathanael	ELLUL	√	√	√	
Norway	Solveig	AAMODT				√
Norway	Marie Johanne Dahlberg	PERSSON	√	√		
Poland	Krzysztof	DOMAŃSKI	√	√	√	
Poland	Monika	WASIAK-GROMEK	√	√	√	
Poland	Łukasz	BELKIEWICZ				√
Portugal	Isabel	LAGINHA	√	√	√	
Romania	Nicoleta	CAROLE	√	√	√	
Slovakia	Lucia	MURÁNIOVÁ		√	√	
Slovakia	Mária	ŠKULTÉTYOVÁ		√		√
Slovakia	Martina	ZATKOVA	√	√		
Slovenia	Tatjana	HUMAR JURIČ		√	√	
Slovenia	Marta	PAVLIC CUK		√		√
Spain	Maria Elena	SANCHEZ DIAZ		√	√	
Spain	Laura	ZAMORA NAVAS	√	√		
Sweden	Karin Margareta	ALKELL	√	√		
Sweden	Åsa Maria	ALMKVIST				√
Sweden	Jonas	FALCK		√	√	
Sweden	Anneli	RUDSTRÖM		√		
The Netherlands	Mattheus Josephus	DE KORT	√	√		
The Netherlands	Femke	VAN DRIESTEN - AFFOURTIT		√	√	
The Netherlands	Lizette Marika Elvira	WELGRAVEN		√		√
The Netherlands	Eveline	BEIJ		√		√

Invited speakers

	Invited Speakers		REACH Workshop	HelpNet Steering Group meeting	CLP Workshop	BPR Workshop
	First Name	Last Name	(2/04)	(3/04)	(4/04)	(4/04)
EU - OSHA	Elke	SCHNEIDER	√	√		
Italy	Renato	CABELLA				√

European Commission

	European Commission		REACH Workshop	HelpNet Steering Group meeting	CLP Workshop	BPR Workshop
	First Name	Last Name	(2/04)	(3/04)	(4/04)	(4/04)
DG GROW	An	JAMERS			√	
DG SANTE	Mario	NAGTZAAM*		√		
DG SANTE	Ligia	NEGULICI *		√		
	* Remote participant					

Stakeholders/Observers of HelpNet

	Observers		REACH Workshop	HelpNet Steering Group meeting	CLP Workshop	BPR Workshop
	First Name	Last Name	(2/04)	(3/04)	(4/04)	(4/04)
AISE	Roberto	SCAZZOLA		√	√	
Cefic	Amaya	JÀNOSI	√	√	√	
Cefic	Ossi	KASURINEN				√
CEPE	Janice	ROBINSON	√	√	√	
ORO	Kevin	HOBAN	√	√	√	
SMEunited	Malte-Matthias	ZIMMER	√	√		

Third Countries - Observers

Country	Third Country Observers		REACH Workshop	HelpNet Steering Group meeting	CLP Workshop	BPR Workshop
	First Name	Last Name	(2/04)	(3/04)	(4/04)	(4/04)
Montenegro	Ilija	GOJOVIĆ	√	√	√	
Montenegro	Ilija	RADOVIĆ	√	√		√
Montenegro	Dušan	RASPOPOVIĆ	√	√		√
Serbia	Snezana	JOKSIMOVIC	√	√		√
Serbia	Aleksandra	RASOVIC	√	√	√	
Turkey	Dilek	ERKAN	√	√	√	
Turkey	Eylem Özlem	NALBANTOĞLU	√	√	√	

ECHA staff

ECHA		
Unit	First Name	Last Name
A.1 Communications		
	Johanna	SALOMAA-VALKAMO
A.2 Support and Enforcement		
	Maciej	BARANSKI
	Patricia	BRILLAS
	Erika	BURAI
	Anisa	KASARUHO
	Olena	KRYCHEVSKA
	Christina	LOUKOU
	Viorica	NAGHY
	Johan	NOUWEN
	Sorina	PARASCHIV
	Anna-Liisa	PIKKARAINEN
	Claudio	PUTZU
	Pedro	ROSELLÓ VILARROIG
	Virve	SIHVOLA
	Nicola	TECCE
	Outi	TUNNELA
	Ana	VALLEJO CORTES
	Laura	WALIN

A.3 Submission and Processing		
	Daniele	APE
	Daniel	SOMPOLSKI
A.4 Data Availability		
	Catherine	CORNU
	István	MÁK
	Alexis	QUINTANA-SÁINZ
B.2 Computational Assesment		
	Anita	RYNKANEN
B.3 Prioritisation		
	Hannu	BRAUNSCHWEILER
B.4 Exposure and Supply Chain		
	Petteri	MAKELA
	Andrew	MURRAY
	Fesil	MUSHTAQ
	Monique	PILLET

Annex II - Action points

REACH Workshop

No	Action	Agenda item	Responsible	Due date	Status
1	Share the draft decision template illustrating how to address concerned registrants with different tonnage bands.	1.3	ECHA	25 April	Closed
2	Feedback on communication on restrictions. If a leaflet is needed, then in which format (paper or web version) and for which audience (general public or national helpdesks) and are there any specific topics where a leaflet would be particularly useful?	1.5	HelpNet	10 May	Closed
3	Share the report of the Commission workshop of 18 March 2019 on the REACH Review once it is made available.	3.3	ECHA	July 2019	Closed
4	Share the report of the combined project with Industry on SDS, on-going this year.	3.3	ECHA	Q1 2020	Closed
5	Reply to the questions on communication in the supply chain.	3.3	HelpNet	July 2019	Closed
6	Promote ENES and Review Action 3 in HelpNet, by including agenda item in the next Steering Group meeting or relevant regulatory workshop.	3.3	ECHA	Q4 2019	Open

14th HelpNet Steering Group meeting

No	Action	Agenda item	Responsible	Due date	Status
1	Revise the HelpNet Handbook (selection of Chair, eventually, the simplified FAQ procedure)	1.1, 4.2	HelpNet members	Q3 2019	Open
2	Vote on the proposals for a simplified FAQ procedure. The written procedure will be launched by the HelpNet Secretariat in April.	4.2	HelpNet	May 2019	Closed
3	Inform the Commission about the feedback received from national helpdesks (NHDs)	5.1	ECHA	April 2019	Closed
4	Provide further clarification on the decision by the General Court in T-837/16.	5.2	ECHA	-	Pending with the Commission
5	Consider communicating to the registrants about the change of follow up of the dossier evaluation process and the transition from the old process using "statements of non-compliance" ("SONC") to the use of Art 42(1) decisions on non-compliance ("DONC") and & "Failure to respond" ("FTR") notification letters.	6.1	ECHA	Q2 2019	Closed
6	Follow up on suggestion of making available Forum HelpEx Q&As of interest also to HelpNet.	6.1	ECHA	Q3 2019	Open
7	Explore possibility of NHDs visiting each other.	7.2	ECHA	2019	Closed

CLP Workshop

No	Action	Agenda item	Responsible	Due date	Status
1	View and provide comments on CEPE's guidance on labelling of treated articles.	1.2	ECHA, NHDs	1 July 2019	Closed
2	Send further proposals and comments about the update of the Guidance on the Application of the CLP Criteria.	2.2	NHD	31 May 2019	Closed
3	To replace the existing Forum Manual of Conclusions in S-CIRCABC with the latest version.	3.1	ECHA	July 2019	Closed
3	Legal review of the interpretation of Article 29(1) and (2).	4.1	ECHA Commission	31 May 2019	Closed Open
3	Confirm DG GROW's most recent view on nail and lash glue products (whether or not they are considered as cosmetics).	AOB	Commission	Q3 2019	Open
6	Confirm Commission's view on the potential inclusion of fuels in Annex II to CLP.	AOB	Commission	Q3 2019	Open
7	Share the information about the upcoming ECHA Conference including the instructions on how to follow online.	AOB	ECHA	30 April 2019	Closed

BPR Workshop

No	Action	Agenda item	Responsible	Due date	Status
1	Share the BPRS Manual of Conclusions with the BPR national helpdesks and the BPR Swiss helpdesk, subject to agreement of the BPRS.	2.2	ECHA	May 2019	Closed