Minutes of the 11th HelpNet Steering Group meeting, Regulatory Workshops and IT Tools Training sessions

Time: From 5 to 6 April 2016

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

Disclaimer

Please, note that the text of the BPR, CLP and REACH Regulation is the only authentic legal reference and that the BPR, CLP and REACH workshop summaries do not constitute legal advice. For further advice contact your national helpdesk.

Table of Contents

1. IT Tools training for REACH and CLP helpdesks

Vasileios TSIFOUTIS opened the IT tools training welcoming the representatives of REACH and CLP national helpdesks, observers and invited experts and introducing the three sessions of the training: Chesar, IUCLID and REACH-IT.

The event started with a presentation of Chesar, giving an overview of the tool and its main functionalities, including a description of an assessment workflow and a short live demonstration. Emphasis was given on the standardised approach in carrying out the Chemical Safety assessment (CSA) and generating the Chemical safety Report (CSR) and Exposure Scenarios (ESs), the improved communication between Chesar and IUCLID in exchanging information, its quick and easy installation process and its zero cost.

The participants were informed about the Chesar training events being planned in the near future with the first ECHA webinar taking place on 21 June 2016. At the end of the session, participants were invited to consider if a more focused training event on Chesar would be needed in their countries in order to promote further the use of the tool and explain its benefits to industry users, especially to Small and Medium Enterprises (SMEs).

The second session was dedicated to IUCLID and it started with a presentation introducing the main changes in IUCLID 6. The new OHTs[1] and how they are implemented in different sections in IUCLID 6 were presented together with an illustration on how to create/import a IUCLID dataset, create a dossier and verify its completeness with the Validation assistant. This served as a bridge to the hands-on exercise that followed, where the participants were asked to download and install IUCLID 6, import a pre-filled dataset, check inconsistencies by running the Validation assistant, correct the identified failures and finally create a IUCLID 6 dossier.

The exercise was well received by the participants who also had the chance to interact with ECHA staff helping them out during the exercise, with specific technical questions. The session ended with an overview of the supporting material that will be made available together with the release of IUCLID 6 (i.e. embedded help system in the application, new streamlined and simplified user manuals available on the ECHA website, short video tutorials). It was also announced that webinars have been scheduled for the end of May - on the transition from IUCLID 5 to IUCLD 6 (for advanced users) - and another one in October.

The third and final session of the event was dedicated to REACH-IT. Short videos introducing the new user interface and the new functionalities (e.g. the substance and tasks pages) were shown, with a live narration from the ECHA presenters. Brief examples on how to submit a dossier in the simplified and improved submission wizard were illustrated, together with the revamped company management module. Finally, a brief overview on OSOR[2] and how this is implemented in REACH-IT took place.

Participants requested access to the industry side of REACH-IT for national helpdesks, in order to be able to view what companies see and be able to assist them. ECHA replied that there have been discussions about this in the recent past, but at the moment this was not possible (system still under development and not stable enough to have a concrete discussion on this possibility). Questions were also raised concerning the translation of the system. ECHA replied that the help text will be integrated in the new REACH-IT and will be gradually available in all EU languages, replacing the user manuals that are now available in ECHA’s website.

Finally, a short discussion concerning the online dossiers took place, and ECHA explained that the Classification & Labelling notification and the member registration dossier (new!) will be available with the first release of REACH-IT in June and that the online inquiry will follow in a later version.

[1] OHTs - OECD Harmonised Templates
[2] OSOR - one substance one registration

2. IT Tools training for BPR helpdesks

Ruben GONZALEZ VIDA opened the IT tools training welcoming the representatives of BPR national helpdesks, observers and invited experts and introducing the two sessions of the training on IT tools:

- Upcoming IUCLID 6 version and IUCLID 6 hands-on training session
- R4BP 3 future developments and hands-on training on R4BP 3 and the SPC editor

During the first session, attendees had the possibility to learn about new features in: IUCLID 6, and substance datasets; BPR dossier creation in IUCLID 6; and the IUCLID 6 release plan. The presentation was followed by hands-on training where attendees had the possibility to install IUCLID 6 and get acquainted with basic knowledge on how to create a substance dataset, how to build a mixture dataset and dossier creation.

During the first session, the following issues were clarified:

- IUCLID 6 will not be ready for the generation of a biocidal product family (BPF) when the new SPC is implemented in October; the supporting manual will be available in the help section in IUCLID 6 as well as in the customary manuals; a dissemination plugin assistant is not foreseen to be released this year.
- The validation assistant in IUCLID did not cover the validation of national authorisation applications which is within the responsibility of MSs according to the BPR: MSs should agree on common validation criteria across Europe in the relevant forum.
- Document I (overall summary and assessment) and document II (risk characterisation, effects and exposure for both the active substance and biocidal product) can be provided in the same template.
- Information requirements are the same in active substance dataset, but special attention should be made when there is a need to change from active substance to non-active substance templates, since information requirements differ greatly.

During the second session, participants learnt about upcoming changes on the implementation of the Review Programme regulation, the adaptations to IUCLID 6 format and the changes in the SPC editor. The hands-on training exercise on R4BP 3 and SPC editor focused on common issues experienced by R4BP 3 users, such us the conversion from frame formulations to biocidal product families, authorisation holder transfer, grouped applications, delegations, nominations and current search capabilities in R4BP 3.

Participants had the possibility to use the SPC editor and a special exercise for authority users giving them the possibility to understand better the interaction between industry and authority users in R4BP 3. They learnt that the migration will take care of the new SPC schema for biocidal product families and that: (i) ECHA is currently working on amending the translations that MSs provided to ECHA for translation of SPCs (summary of product characteristics); (ii) The C&L information will be removed from the SPCs (in October 2016) as this is information already covered in the product assessment report (PAR) and that due to constant development of the SPC schema this information cannot be shared with authorities to build a parallel database system to keep track of on-going SPCs.

Participants were keen on seeking clarification also on topics that were beyond the scope of the exercise (i.e. search criteria in R4BP 3, scope of the validation in MS or practical implications of authorisation holder transfer) and practical issues they had received from applicants in their countries (i.e. criteria to be considered when creating an SPC for simplified authorisation, how to process an application in R4BP 3 when minor information outside the standard workflow is needed or how to submit correctly a notification for simplified authorisation in a different MS). On request the testing material will be made available on S-CIRCABC for further practise.

The participants valued the opportunity to hear about the latest development of IT tools and test how the BPR processes have been technically implemented and updated.

3. REACH Workshop

3.1. Annual evaluation report

Lee WALKER (ECHA) presented the progress made in ECHA's evaluation work in 2015 - dossier and substance evaluation - as resulting from the 'Evaluation report 2015', published by ECHA on 25 February 2016.

In 2015, ECHA implemented its current compliance check (CCh) strategy and concentrated its dossier evaluation activities on substances that matter the most for human health and the environment. The use of complementary measures played an important role in improving the overall dossier quality under the current compliance check strategy - as for example, publication of a periodically updated indicative list of substances that may be selected for CCh, a letter campaign targeted to registrants with potential deficiencies in their dossiers, etc.

With the help of Member States, ECHA improved the selection of substances of concern by using an integrated selection and priority setting approach enabling the identification of substances with potential concern that may require further scrutiny.

Following the amendment of Annexes VIII, IX and X to the REACH Regulation, the extended one-generation reproductive toxicity studies (EOGRTS) were incorporated in the REACH information requirements in March 2015. Since then, ECHA has started to address the EOGRTS information requirement in the evaluation dossiers.

Regarding testing proposals, ECHA promoted the use of alternative methods and started requesting and publishing the registrant's considerations on alternatives to their proposed vertebrate testing as part of the third party consultation. ECHA published the Read-across Assessment Framework (RAAF) providing a framework for a consistent and structured assessment of grouping and read-across approaches under REACH.

In his concluding remarks, Lee WALKER invited NHDs to make use of the information contained in the report[3], particularly conveying the recommendations given to future registrants - preparing their registration dossiers for the first time - and to existing registrants potentially identifying shortcomings in their dossiers and planning to update them.

In the following discussions, one NHD referred to a case where all members of a SIEF received a letter highlighting a potential concern of the registered substance. It was assumed that one member of the joint submission could have reported the presence of an impurity in the composition of the substance, possibly leading to a carcinogenic, mutagenic or toxic for reproduction (CMR) classification. A clarification was requested on the action undertaken by ECHA to send all registrant of the joint submission the acknowledgment letter and Lee WALKER promised to come back with a response[4].

One NHD representative recommended that when ECHA letters are sent to registrants, there should be a clear indication, who (i.e. which registrant) is concerned and what is the concrete concern to be looked at.

[3] Evaluation Report 2015: http://echa.europa.eu/documents/10162/13628/evaluation_report_2015_en.pdf

[4] In some cases, substances might be selected for manual verification due to the presence of a harmonised reproductive toxicant and carcinogen in one/few registration(s) of the joint submission. In the particular case presented, the substance was selected on the basis the composition potentially containing a harmonised reproductive toxicant (1A/1B) above the concentration limits. Consequently, a letter was sent to all registrants of this substance highlighting the potential concern. When a substance is short listed, then the primary reasons for short listing are communicated to all registrants of the substance. This is to ensure transparency to all and to facilitate discussions in the SIEF. The letters do not include potentially confidential information.

3.2. State of play of the guidelines for the restriction of polycyclic organic hydrocarbons (PAHs), nickel and lead

In October 2014, the Commission requested that ECHA develop guidelines on three restriction entries (nickel, polycyclic aromatic hydrocarbons (PAHs) and lead) aiming to clarify which articles and subtypes of articles fall under the scope of these entries.

Kirsi SIHVONEN (ECHA) presented the state of play of the draft guidelines targeted to NHDs, competent authorities responsible for implementation and enforcement, and stakeholders.

- The lead and its compounds guideline has been discussed and endorsed at the March 2016 CARACAL meeting and will be published soon; it relates to substances in articles supplied to the general public but does not cover the part adopted earlier and related to lead and its compounds in jewellery articles. It clarifies the interpretation of certain aspects of the scope of the restriction related to lead and its compounds in articles, e.g. what is regarded as reasonably foreseeable conditions of use and gives examples of article types covered or outside the scope of this restriction, as for example tin figurines for collectors.
- The PAHs and nickel guidelines will also clarify the definitions of these entries including the meaning of 'placing on the market for supply to the general public' already discussed in the CARACAL meetings of November 2015 and March 2016. The guidelines will be updated after receiving the final legal interpretation from the Commission; it will be opened for public consultation and re-discussed in CARACAL for endorsement. The aim is to publish the guidelines by the end of 2016.

The guidelines will be published under Q&As on restrictions section[5] on ECHA website. It was further clarified that the document updated by the Commission after consultations with CARACAL, containing Q&As on restrictions was handed over to ECHA by the Commission a few years ago. Currently, there are two sources for the Q&As on restrictions on the ECHA website: most of the Q&As are drafted by ECHA in close collaboration with the Commission while the others come from HelpNet proposals. Whenever the endorsement of CARACAL is needed they are submitted and discussed in those meetings.

3.3. ECHA's strategy to support registrants in the application of the REACH Annex III criteria

Alberto MARTIN APARICIO (ECHA) presented the Agency's strategy to support registrants in the application of the REACH Annex III criteria.

ECHA is currently preparing an inventory of about 68,000 substances that are likely to meet the Annex III criteria. Therefore, potential registrants of those substances may need to submit a full Annex VII registration dossier for their 1-10 tonnes/year substance (and not a 'light' physico-chemical dossier).

The inventory is expected to be released in May 2016 and has an advisory purpose which will not prevent a registrant from submitting a 'light' physico-chemical dossier if they are entitled to do so. A new section in IUCLID 6 will allow registrants to justify why they consider that a registration qualifies for these reduced information requirements. In addition, ECHA is preparing case studies and supporting technical documentation.

Despite initial concerns that the inventory may add additional burden on companies, especially on SMEs, one NHD voiced its appreciation for the work carried out by ECHA and the way this strategy was incorporated in IUCLID 6.

[5] ECHA website>>Q&As: http://echa.europa.eu/support/qas-support/qas REACH>>Restrictions

3.4. Update on ENES & CSR/ES[6] roadmap activities

Bridget GINNITY presented the results of intensive work carried out by ECHA and MSs to improve communication on the safe use of chemicals in the Chemical Safety Report (CSR), exposure scenario (ES) and downstream user communication (DU) areas. She highlighted that the following achievements which will be beneficial for registrants, CAs and DUs:

- CSR/ES Roadmap projects:

    - Interactive 'Infograph' which illustrates in a clear manner the Roadmap products available to industry for improved upstream and downstream communication on use and exposure information;

    - Use maps[7] package: informs on the uses of chemicals in a harmonised and structured way. It describes the uses and has links to the information needed to carry out exposure assessments. The concept was developed by industry in 2009. It has now been reviewed and updated. The use maps package consists of four templates:

    - Templates provided for each element of the use map package and a new webpage describing use maps. One template covers the description of use, and three deal with input data sets for the exposure assessments of workers (SWEDs), environment (SpERCs) and consumers (SCEDs). All templates and guidance are finalised except SpERC.

- Improving communication on mixtures:

    - Two complementary approaches have been developed to communicate information on mixtures. One is a sector-based approach to develop generic sets of realistic and consistent safe use information for typical mixtures, called Safe Use of Mixtures Information (SUMI).

    - The other approach is to identify the lead components of the mixture for the various exposure routes or pathways, called Lead Component Identification (LCID) methodology.

- DUs support:

    - 'Tips for users of Chemicals in the work place' document[8] developed by the HelpNet working group and ECHA. The document is a short guide for users of chemicals in the workplace on how to get the most from the classification and labelling information they receive.

- HelpNet Working Group on developing integrated support for downstream users:

    - The working group consisted of members of the national REACH and CLP helpdesks from DE, IE, NL, FR, a DUCC representative and ECHA colleagues.

    - Objectives: identify the needs of DUs, measures to fulfil their needs; develop material to support these measures; promote identified solutions among HelpNet members and identify and share best practice on integrated support for DUs.

    - Output: the publication 'Tips for users of Chemicals in the work place'

She encouraged NHDs to use and promote the publication and consider if other activities would be suitable for the working group to continue, eventually compiling Q&As, providing input to

[6] Chemical safety report / Exposure scenario roadmap: http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap
[7] Use maps: http://echa.europa.eu/csr-es-roadmap/use-maps
[8] The English version of the document was published on ECHA's website and will be available in all languages: http://echa.europa.eu/documents/10162/966058/tips_users_chemicals_workplace_en.pdf

ECHA's DU communication strategy (agenda point 6.2), etc.

3.5. Substances in Articles - 0.1 % SVHC European Court Judgment (ECJ) - support to companies

Suzanne WIANDT (DE) introduced the topic, by referring to previous discussions on REACH requirements for substances in articles (SiA), ECHA's legal view and the formerly dissenting views expressed by several Member States (MSs) at the 2015 REACH workshop[9].

She described how the German HD have been supporting companies since the ECJ[10] in September 2015, specifically by publishing information material[11] for suppliers of articles - i.e. producers, importers, retailers of articles; publishing new FAQs and updating the HD website with a section on 'Articles'; being actively involved in various events, e.g. webinars, seminars and explaining to duty holders how the ECJ applies in relation to registration and notification (Article 7(2)), and in relation to article supply chain communication (Article 33 of REACH).

NHDs welcomed ECHA's fast track update of the SiA guidance published last year following the ECJ, but voiced some disappointment regarding the more detailed update which would only be available at the end of 2016 (beginning of 2017).

Johan NOUWEN (ECHA) and Peter MEGAW (ECHA) emphasized that the draft versions from each stage of the full consultation of the more detailed update will be made available on the ECHA website from summer 2016 onwards. Examples which were removed from the current temporary version will be replaced or updated taking into account feedback from consultation of the PEG members, the Forum for Enforcement and the CARACAL during the three-step consultation taking place during the rest of 2016.

In the interim period, NHDs from the formerly dissenting MSs were recommended by Suzanne WIANDT to seek advice from the document produced by the dissenting Member States (including Germany) which is also available in English (link provided in the footnote).

3.6. REACH 2018 - World Café

Henna PIHA (ECHA) introduced the World Café principles, topics and table hosts:

Laura WALIN and Anisa KASARUHO (ECHA) - hosts for the topics: 'REACH 2018 registration deadline[12], phase 4[13]' and reporting from the REACH 2018 Communicators' network meeting on 4 April 2016.

Summary of discussions:

- Key messages for phase 4 and actions to promote the 2018 REACH registration deadline: If collecting information on uses is done by national industry associations (in different languages) there is a need to further process it at the EU level by the European umbrella organisations so that the compiled information would be available in English;
- Activate the consultants, laboratories who should start marketing their services and therefore would be a channel to activate the registrants;
- Simple and intuitive information on IT tools still to be developed in 2017;
- To highlight the urgency for companies to start preparing their registration dossiers;

[9] HelpNet REACH workshop from 17 to 18 November 2015
[10] Case C-106/14
[11] Guidance for Suppliers of Articles (DE, EN): http://www.reach-clp-biozid-helpdesk.de/en/Publications/Technical_guidance-en/Technical-guidance.html
[12] ECHA's REACH 2018 Roadmap: http://www.echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf
[13] Phase 4 - assessing and documenting hazard and risk information in the registration dossier

there might be a need to publish a concrete registration timeline.

Laurence HOFFSTADT and Eva VALKOVICOVA (ECHA) were the hosts for the topic: 'Gathering feedback on messages to registrants to support registration in 2018'.

In order to support registrants, understand their legal information requirements and to provide them with recommendations and tips, ECHA has reviewed the Evaluation reports issued since 2009.

The group discussed about the most important messages per topic of relevance for 2018 (excluding compliance check / testing proposal evaluation findings).

Summary of discussions:

- Key messages for phase 4: Currently, NHDs are not receiving questions which are relevant to phase 4. The questions are more related to roles (manufacturer/importer) under REACH and rather how not to register by 2018;
- NHDs are requested to provide very practical step-by-step advice; the recommendation is extended to ECHA;
- Need to emphasise the need to decide on registration promptly (what substance can't they live without) and to initiate data gathering;
- Annex III criteria is NOT an easy way out;
- Messages of phases: 1, 2 and 3 need to be re-iterated in 2017.

Henna PIHA and Johan NOUWEN (ECHA) were the hosts for the topic: 'Handling and responding to questions'.

Summary of discussions:

- NHDs indicated that in the majority of countries, no additional resources are foreseen or strategies put in place to manage a possible peak of questions in 2018 as no peak is currently observable;
- Some MS are foreseeing one additional staff to cover the possibly increasing workload;
- The NHDs did not indicate to need additional check-ups in order to identify needs for joint actions (e.g. new FAQs, awareness raising activities, etc.);
- The HelpNet Secretariat encouraged the HelpNet members to use HelpEx actively, also for informing other MS & ECHA of reoccurring questions.

Answer shopping:

- Answer shopping is currently not a significant issue for the NHDs;
- NHDs consider that if answer shopping becomes an issue closer to 2018, we should deal with the matter in a similar way as previously i.e. by posting in HelpEx.

Standard sentence for sending non-EU companies to ECHA:

- NHDs indicated that many of them do not receive questions from non-EU companies;
- If they receive questions from such companies, they reply to them or (e.g. DE) request them to contact ECHA.

3.7. Follow-up of the HelpNet Substance Identity workshop

The Chair introduced the following topics:

3.7.1. Q&A on the technical details for the joint registration of charcoal

The chair informed that the actions taken by ECHA following the Board of Appeal decision in case A-22-2013 for the charcoal registration dossiers will be covered in the presentation given by Theodora BASMATZI, 'Updates from ECHA on BPR, CLP and BPR' (agenda item 6.1.2).

3.7.2. Substance identity - Does limestone which is surface treated with stearic acid have to be registered?

Pawel FIGIEL (ECHA) formulated ECHA's position on the appropriate answer to the query 'if limestone which is surface treated with stearic acid has to be registered' in the form of two options. His explanations could therefore not conclusively resolve the apparent overlap between Q&A number 38 and the Annex V exemptions. Numerous NHD correspondents were less than satisfied by the lack of a clear-cut answer. The HelpNet Secretariat will further consider this case with the Legal unit whereupon Germany as the 'owner' of this question in HelpEx might choose to re-open the question. Ultimately, it might be brought to the Commission for authoritative clarification.

4. CLP Workshop

Outi TUNNELA (ECHA) welcomed the CLP correspondents and observers to the CLP workshop.

4.1. Forum project on child resistant fastenings (CRF)

Erika Burai (Hungary) presented some preliminary findings from the project. She highlighted the need to have the CRF already in the first placing on the market when the intention for the general public is clear, regardless of quantity or size. While the CRF certificate is expensive due to complex testing, the regulation allows for cooperation in the supply chain and sharing the certificate.

No list of CRF manufacturers has been made available due to the risk of unequal treatment, promoting some manufacturers above others. What Hungarian inspectors principally did when they found a non-compliance, is to provide a thirty-day period to obtain the certificate and/or a verbal/written advice. It was also discussed if the manufacturer of the packaging could be considered responsible for providing a fully compliant packaging. However, this cannot be considered a requirement under CLP (as the supplier of the chemical is always responsible for the classification, labelling and packaging of the product they supply).

4.2. Placing on the market in regard to the transitional period for mixtures; Article 45 and Article 48 implementation of CLP

Maria Paleomilitou (Cyprus) asked the participants if they would agree on a flexible interpretation for placing on the market in the context of the transitional period. The aim of this flexibility would be to allow a reasonable enforcement by the Member States. There was a general agreement that the case was clear in case of imports.

At this point the participants were updated on the discussions taking place at CARACAL. There, a proposal to modify an existing FAQ was being discussed, with comments expected by 08/04. ECHA informed that once CARACAL reached an agreement, a new Q&A would be published. As both Commission and Member States will have provided their comments, there would be no need for a HelpNet commenting round. Also, the Commission was still reviewing the definition of 'placing on the market' at REACH and CLP level.

The participants discussed the three cases presented by Maria Paleomilitou with the following views:

- On Case 1a the general view was "yes".
- Case 1b: the agreement was "no". A distributor can benefit from the transitional period as they do not change the mixture.
- Case 2: the agreement was "yes".

The discussion moved on to the responsibility of a re-filler for re-classifying a mixture. It was unclear whether a re-filler would have this responsibility. Sending the product back to the supplier for re-classification was not seen as feasible for actors such as hardware stores.

Some participants wondered if any authority could check if a given actor placing a mixture on the market had correctly notified to the relevant appointed body, following Article 45. It was agreed that the extensive use of an adequate identifier in the label would allow this type of cross-check amongst authorities and MS. The participants acknowledged that it will in any case still take a long time for the unique product identifier to appear on product labels.

When discussing the obligation to provide on the advertisement information on the types of hazards of a mixture sold to the general public, there was general agreement that only when the buyer can finalise the purchase without seeing the product, the hazard type needs to be evident. The next question was about TV advertisements where the purchase is finalised on the phone. When and how the consumer can get the label information?

A correspondent suggested providing the SDS with the product to consumers. This was considered to be too complicated information for a consumer and could lead to problems regarding the languages in which the SDS was provided. However, the availability of an SDS on a website was seen as a good addition (though cannot be mandatory).

4.3. Label size and exceptions

Outi Tunnela (ECHA) updated the participants on the ongoing discussions at several levels. COM's proposal on fold-out labels was open for comments until 08/04. The ECHA guidance on labelling and packaging was under revision, with the Partner Expert Group commenting on readability of labels. COM had implied that this revision would cover also the issue of double labelling. Outi Tunnela highlighted that the overlap with the requirements under the detergents legislation were not properly covered this time.

The Italian correspondent shared their way to deal with re-fills, covering several options to be compliant. Some participants still considered that enforcement would be an issue.

4.4. Open-space discussions

Outi TUNNELA (ECHA) explained that the objective of this session was to draft a background document for the Commission, compiling the present views on each topic. Then it would be up to the Commission to prioritise which topics can be clarified by them and which would need to be addressed at UN-GHS level.

4.4.1. Bridging Principles

The discussion is not minuted, but it was summarised as agreed during the workshop.

4.5. Follow-up on aerosol classification FAQ

Anja KNIETSCH (DE) presented the follow-up actions on aerosol classification. The question remained if the Commission would take on board the proposal for the 10th ATP.

4.6. Timed-out CLP questions - next steps

Outi TUNNELA (ECHA) listed the timed out questions in HelpEx and requested some action from the owners. She added the following the comments to each one of them:

- 12912: There is nothing more to add here. It is an issue for cosmetics legislation
- 12913: There is no legal basis to provide more feedback
- 13010: This question is REACH rather than CLP. No further feedback
- 12905: Suggest to close it with the comment 'will be discussed elsewhere (UN-GHS?)'
- 12941: There is nothing to add to the already provided feedback
- 12580: Will be modified based on Commission's Q&A
- 12375: Can be finalised with the feedback already provided.

4.7. Update on unsolved HelpEx questions

Outi TUNNELA (ECHA introduced the following topics:

4.7.1. Labelling of outer packaging (HelpEx 12322) and Consolidated packages (HelpEx 12323)

Caroline Walsh (Ireland) presented the history of the concept of outer and consolidated packaging. While the discussions at CASG-LP continue, she proposed an interim solution to be established in the ECHA Guidance.

4.7.2. Contact details of the supplier in SDSs (HelpEx 12350)

Outi Tunnela (ECHA) presented the reply from the Commission to the question about the contact details of the supplier in section 1.3 of the SDS. They need to be added in any case, although this should not be considered as an update according to Article 31(9) of REACH.

4.7.3. Any Other Business

Outi Tunnela (ECHA) informed the participants that she would send the draft factsheet on enzymes for comments. She expressly requested to comment on its usefulness, and to consider its further distribution to MSCA and inspectors.

A correspondent pointed out that the new FAQ process' deadlines were hard to follow. The origin could be a faulty e-notification. The correspondent would contact the Secretariat to check if there was an issue on the technical side.

Another correspondent raised a question raised by a company where a DU used a mixture with registered substances. For one of them the LR used a specific concentration level (SCL) of 80% in the registration dossier. The matter was to which extent the DU could use the classification. There was a general agreement that the DU should contact directly the Lead Registrant to clarify the situation and to check if the value could be a mistake.

The 11th HelpNet Steering Group meeting

5. Opening of HelpNet-11

5.1. Welcome by Andreas Herdina

The Chair of HelpNet, Andreas Herdina (ECHA) opened the 11th HelpNet Steering Group meeting by welcoming the REACH, CLP and BPR national helpdesks (NHDs), observers, and associated members. He introduced the newly appointed observers from Switzerland - Olivier BLASER and Brunhilde KOLP BUCHS from the Common Notification Authority for Chemicals.

The names of all participants attending the 11th HelpNet Steering Group meeting, the regulatory workshops and the IT tools training sessions are listed in Annex I of these minutes.

5.2. Approval of the draft agenda, follow-up of action points

The Chair introduced the revised draft agenda and the room documents that were made available to participants:

- The revised draft agenda
- Housekeeping rules
- Draft Handbook

He invited the HelpNet members to express their concerns (if any) on the attendance of observers to particular agenda points and indicate any conflicts of interest they may have. Without further changes, the agenda of the meeting was approved.

The minutes of the 10th HelpNet meeting and workshops were approved and published on ECHA website with one exception: the minutes of the REACH workshop held from 17 to 18 November 2015 which will be finalised after this meeting, subject to one clarification[14] on the topic 'Surface treated limestone'. All the follow-up actions related to the previous meeting and workshops were closed.

5.3. Introduction of new HelpNet observer: Swiss Common Notification Authority for Chemicals

Olivier BLASER (Switzerland) thanked for the opportunity given to the Swiss Common Notification Authority for Chemicals[15] to participate in the work of HelpNet and explained the set-up of the Swiss national helpdesk within his organisation.

The Common Notification Authority is the federal hub for chemical products having a coordinator and administrative role in the authorisation of chemical products and biocides process. It is hosting the BPR helpdesk a body established by the Swiss government to support companies, industry associations and SMEs.

In reply to a question from participants, the Chair clarified that, on the basis of the amended Mutual Recognition Agreement between the EU and the Helvetic Confederation in 2015, the ECHA Management Board invited Switzerland to participate in the Agency's biocides-related work only. Therefore, Switzerland will not be taking part in the CLP and REACH activities.

[14] An agreement is sought on the final wording of FAQ 38.
[15] http://www.bag.admin.ch/anmeldestelle/index.html?lang=en

5.4. HelpNet Handbook

The Chair introduced the second version of the 'HelpNet Handbook'. The document is describing the functioning of the network and integrates all documents previously in use. The document remains classified as internal as there is no perceived need to make it available to the public.

The text of the handbook was finalised after two rounds of written consultation[16]. The feedback received from HelpNet members and responses from the HelpNet Secretariat were summarised in Annex I. One important amendment will allow accredited stakeholders who do not provide a helpdesk as such to become members of the network.

The meeting adopted the 'HelpNet Handbook' replacing the documents: Rules of procedure of the HelpNet Steering Group; Mission statement of the BPR, CLP and REACH Helpdesks Network (HelpNet); Step-by-step guide on the publication of Frequently Asked Questions (FAQs) on BPR, CLP and REACH on the ECHA website; and Step-by-step guide on addressing issues for further consideration, and thus making the procedural provisions ruling the work of the HelpNet more easily accessible and readable.

5.5. HelpEx tips and tricks

In her presentation, Iris BRIAT (ECHA) introduced the 'Quick HelpEx Guide' which was created to replace the 'HelpEx Manual' and facilitate the use of the HelpEx tool by NHDs. She also announced two WebEx training sessions on the use of HelpEx scheduled on 21 and 27 April, explained how to set alerts (email notifications) for FAQ proposals, and how to filter for entries on the FAQ platform.

ECHA and several HelpNet members had observed less activity by NHDs during the FAQ consultation rounds than in the years before. Following the suggestion by Suzanne WIANDT (DE) that the many commenting deadlines could be a reason for that[17], Iris BRIAT clarified that it would be possible to have the same cut-off dates for all regulations, which would subsequently reduce the number of commenting deadlines. Henna PIHA expressed that this option would be favourable also from ECHA's side.

The participants raised no objections when the Chair suggested moving harmonised cut-off dates and deadlines for the BPR, CLP and REACH.

5.6. National helpdesk activities 2015

The Chair thanked the HelpNet correspondents for actively reporting on past and future activities undertaken by NHDs.

The draft version of the report will be circulated for fact checking and for NHD input to the conclusions that the report will draw. These will be grouped around three topics:

- NHD statistics showed that biocides-related questions have continued to rise in number, specifically by 38% between 2014 and 2015 alone
- CLP questions also increased, linked to the mixture deadline in 2015
- REACH-related questions remain more constant in numbers, but intensify in complexity

In view of the fact that helpdesk resources are not solely dedicated to answering questions, but also contribute to other activities (e.g. events and the elaboration of guidance, etc.) both at national as well as ECHA Helpdesk levels – feedback that most NHDs are coping with

[16] The two rounds of consultation run by June 2015 and March 2016.
[17] At the 10th HelpNet Steering Group meeting the participants had decided that they would want to have the cut-off dates for FAQ proposals in a different month for each regulation.

unchanged resources and some even had to cope with resource cuts constitute an important message to management and policy makers.

Other findings will need to be resolved through changes to the collaboration between NHDs and customers to keep up with the social media evolution such as, for instance, the increased reliance of companies on information provided through various media channels (e.g. Twitter, YouTube, etc.).

A number of proposals in the 2015 report have already been addressed by ECHA. Some others might need further consultation within ECHA before the conclusions are drawn-up and included in the annual report.

The HelpNet Secretariat proposed correspondents to establish a 'Sounding Board Group' of NHDs who could virtually meet and conclude together on the follow-up actions to be included in the report. The group could also support the long planning of HelpNet activities.

5.7. Evaluation of the Hellenic helpdesk by its end-users, during CLP training activities organised in 2015

Christina TSITSIMPIKOU (EL) presented the results of the evaluation of the Hellenic NHD for REACH, CLP and BPR. The Hellenic competent authority conducted a survey in the framework of the annual training workshop for REACH and CLP inspectors, targeted to industry (producers, importers, downstream users, distributors), public sector, non-governmental organisations, consultants and consumers.

Overall, the performance of the Hellenic NHD was well-rated. Statistics on the break-down of its activities - i.e. availability of the Hellenic NHD, communication with the NHD (most frequently by phone calls, 69%), level of expertise, satisfaction with the responses to enquiries, training activities and geographical distribution – made this particularly interesting.

5.8. Questions & answers session

In some member states the support of the enforcement authorities, Enterprise Europe Network partners and industry associations in responding to customers' enquiries makes the number of reported responses to look less than one may expect. Also, phone calls are not always recorded and reported although for some NHDs this is the most important and efficient way to support industry, at any time during the business hours, without the burden of bureaucratic or heavy procedures.

Further discussion took place on the process of revising FAQs and the advantages and disadvantages of having quarterly updates for each regulation per year. The reduced activity on HelpEx might be triggered not only by technical difficulties for some of the HelpEx users but might be due to the high number of already existing Q&As published. Thus, it was questioned if the current FAQ procedure can be amended (e.g. reducing the number of updates) or other relevant activities (e.g. awareness campaigns, communication activities) might be needed in the future.

6. Updates from the European Commission and ECHA

6.1. Recent regulatory developments

6.1.1. Updates from the European Commission on CLP and REACH

Temenuzhka POPOVA (COM - DG GROW) joined the meeting by video-link from Brussels. She informed on the Implementing Regulation on data-sharing[18] and costs related to letter of access; simplification of the authorisation application process under REACH; restrictions published and in the pipeline; the negative opinion of the Regulatory Screening Board on amending the REACH Annexes to include provisions on nano-materials; the state-of-play of numerous ATPs for CLP. She also outlined the various studies conducted or still ongoing in preparation of the Commission's Article 117(4) REACH Review due in June 2017 as well as the forthcoming vote on the harmonisation of poison centres; participation in the fitness check of non-REACH chemicals safety legislation (including CLP). She encouraged NHDs to participate in the public consultation[19] and contribute to the study on CLP and related legislation.

6.1.2. Updates from ECHA on BPR, CLP and BPR

Theodora BASMATZI (ECHA) informed on the various changes made by ECHA in response to the Commission's Implementing Regulation on data-sharing and joint submission imposing a stricter implementation of the OSOR principle (also via the respective new IUCLID 6 functionality); the ongoing review of the completeness check of registration dossiers; the impact of ECHA's Board of Appeal decision in the appeal case A-22-2013 brought by the lead registrant of charcoal against ECHA's decision finding complete and assigning a registration number to an individual registration of charcoal; and data sharing and enforcement aspects related to Article 95 of BPR.

6.2. Updates of on-going ECHA activities

6.2.1. Guidance activities

Peter MEGAW (ECHA) gave an overview of the two year guidance moratorium ahead of the 2018 REACH Registration deadline and of the guidance updates under consultation[20] or foreseen to start in 2016.

For the moratorium starting on 31 May 2016, some exceptions will apply, e.g. in cases when the legal text is amended, IT tools updated and time for consultation is still needed.

6.2.2. Downstream user communication

Mikko VÄÄNÄNEN (ECHA) outlined the Downstream User (DU) Communications Strategy, aiming to provide user-friendly and comprehensive information for DUs on their roles, obligations and the tools available to help them on the ECHA website in 23 EU languages.

[18] Implementing Regulation on data-sharing:
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN
[19] Public consultation: http://ec.europa.eu/yourvoice/consultations/index_en.htm
[20] Ongoing REACH, CLP and BPR guidance consultations:
http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach
http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-clp
http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-bpr

He outlined the main objectives of the DU communications, the communication channels (media campaigns, products[21] developed with partners, presentations used by multipliers, social media, etc.) for outreach the target audience and the partners ECHA is relying on (accredited stakeholders, sector specific associations, 2018 REACH communicators' network, EEN, HelpNet, Forum, etc.) to spread the messages and raise awareness.

The Chair outlined the importance of the DU communications strategy - as important as the REACH 2018 one - and invited NHDs not represented in the 2018 REACH communicators' network yet to join the group.

One intervention from the floor appealed to keep the DU information on the ECHA website at a level understandable and useable by SMEs.

6.2.3. Forum activities

Maciej BARANSKI (ECHA) provided an update on the results and content of the numerous REACH Enforcement Projects (REF) and pilot projects that the Forum has concluded or launched more recently:

- REF-3: Registration obligations and cooperation with customs; 1169 companies checked, 5746 substances in 28 countries; final report published in 2015
- REF-4: focus on 14 restriction entries; inspections ongoing, report expected in 2017 (Q4)
- REF-5: Extended safety datasheets, exposure scenarios, risk management measures and operational conditions; operational phase to start in 2017 and report expected in 2018 (Q4)
- Pilot 1 on authorisation; 421 inspections in 18 countries; report published in February 2016
- Pilot 2 on authorisation; operational phase to start in January 2016; report expected in mid-2017
- Pilot on child resistant fastenings; 797 inspections; report expected in mid-2016
- Pilot on CMRs and skin sensitisers; report expected mid-2016
- Pilot on CLP focusing on internet sales of mixtures; report expected in 2018 (Q1)
- The pilot project on 'Obligations for substances in articles' was already decided to start in late 2017, addressing Court of Justice decisions on SiA from 2015.

He also informed the participants that stakeholders were invited to make proposals for the future Forum projects by middle of April.

Regarding enforceability of restrictions, Forum recently finalised published the following documents on the ECHA website:

- Forum Working Procedure for the Elaboration of Forum advice and Support to RAC and SEAC on Enforceability of Annex XV Restriction Proposals
- Forum guide on Enforcement for Dossier Submitters
- Compendium of analytical methods - recommended by the Forum to check compliance with REACH Annex XVII restrictions; NHDs were invited to provide information that can be included in its future revisions (e.g. suggestions of new methods)
- Methodology for recommending analytical methods to check compliance with REACH Annex XVII restrictions.

Last, but not least he invited the REACH HelpNet members to the Forum training for trainers, taking place from 5 to 6 October 2016, in Helsinki, in parallel with the REACH HelpNet

[21] For example: posters, postcards, leaflets for companies, joint webinars or events.

workshop. Invitations and details will follow in due course.

The Forum-23 plenary in March 2016 was also the first meeting to be organised back to back with the Commission's Biocides Enforcement Group (BEG) to discuss BPR enforcement priorities and activities on the national level. The BEG was formed with the view to ensure smooth transition of BPR enforcement into the Forum. The future of coordinating BPR enforcement will be discussed in more detail in the BEG meeting in June. Thus, many BEG members and the Forum support the full integration of BPR into the remit of the Forum.

6.2.4. Questions and answers

Outi TUNNELA (ECHA) reported on the discussion on 'Contact details of the supplier in SDSs' that took place at the CLP workshop (see agenda item 4.7.2 and the Commission's position). One NHD expressed its disappointment with the Commission's reply, and indicated that they still wish to take the issue up in future discussions with the Commission.

7. SME support

7.1. SME visits programme

The Chair presented the SME visits programme conducted by ECHA between September and November 2015, highlighting the main findings and the valuable feedback received from the visited companies.

The event was a training event targeting junior staff of ECHA. 41 staff members had the opportunity to gain real-life insights into the business of SMEs by visiting 39 companies in twelve Member States.

The composition of volunteering companies does not reflect a representative cross-section of SMEs, but was generally biased towards companies that actively interact with networks such as European Enterprise Network (EEN) and the Agency's Accredited Stakeholder Organisations representing industry.

Some findings showed that certain companies do not rely on NHDs but rather on business associations, while some others consult the webpages of their national competent authorities. They are generally well informed about the REACH 2018 registration deadline, but have limited resources to dedicate to REACH and cannot afford specialised consultants. For them following legislative changes is a challenge and sometimes they are not even aware of the fee reduction SMEs are entitled to. The Chair encouraged NHD to promote the self-calculation tool[22] provided by ECHA.

A company suggested that information on the SME criteria should not only be provided on the ECHA website, but also appear in the submission tool, itself. This was followed-up and the new release of REACH-IT in 2016 will include this feature.

Generally, visited SMEs acknowledged the importance of communication in the supply chain which has noticeably improved. However, the accuracy and quality of eSDS still needs special attention or correction by larger companies, especially when data is coming from smaller suppliers.

Some companies highlighted the positive effects of the CLP Regulation, resulting in improved communication about hazard information and empowering companies to demand detailed SDSs from their suppliers. They mentioned a number of shortcomings, as well: e.g. some

[22] How to determine the company size category: http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category

companies are still confused on how to classify mixtures, substantial investment for labels, transition periods which were seen to be unfair.

SMEs found the BPR particularly burdensome, despite the primary expectation that the regulation would simplify the regulatory regime.

Regarding the ECHA website, a few appreciated the website without any reservation while the others found it overloaded with information and hard to follow. This feedback coincides with the results of ECHA's recent customer insight survey which is being taken as input for re-designing the structure of ECHA website. Numerous visited companies however appreciated ECHA's dissemination portal.

The Chair mentioned that the 'Findings from the SME Visits Programme' document shall be used by NHDs for internal use only.

7.2. SME campaigns in Member States

The Chair opened the session and invited the NHDs to express their views on campaigns targeted to SMEs in their countries.

7.2.1. Danish experience

Anders SKOU (DK) highlighted the fact that typically small Biocides producers are still unaware of the Biocides legislations and of the obligations that it imposes on them. These small and often micro companies are difficult to reach. Currently, with the support given by Danish consultants, the NHD is mapping the state of the art. He will report back on this ongoing project.

7.2.2. Dutch experience - Website for SMEs

Margaret WOUTERS (NL) introduced the new product developed by the Dutch NHD as a means to support SMEs in meeting their REACH (registration) requirements. Starting with some fundamental questions to determine a company's role, dedicated new webpages compile a tailor-made roadmap that addresses the specific company's situation and lays out the steps for the potential registrant to take. This tool somewhat resembles ECHA's 'Getting started' webpages, but provides an individualised service going beyond that. The tool developed by the Netherlands can be found at: https://www.chemischestoffengoedgeregeld.nl/

Provided the respective resources can be found, the intention is to make available the website in English too.

7.3. Group discussions and summaries on the profile of helpdesk work

The Chair invited participants to split-up into four groups to discuss SME awareness, effective and innovative means to reach SMEs and keep them informed on legal REACH, CLP and BPR requirements:

1. Effective ways to reach SMEs and examples of national campaigns;
2. Keeping SMEs updated on legal requirements and practical implementation;
3. NHD and ECHA supporting sector associations;
4. National helpdesk visits to SMEs – similar to the ECHA SME visits programme.

In all of these break-out groups the discussion gravitated towards 'reaching the unreachables' that are not organised in sectorial industry associations. Mass campaigns (e.g. postcard campaigns) need to be targeted, for instance to companies who have already pre-registered or by going beyond the chemicals sectors (e.g. stands at trade fairs, placing articles in general

business magazines). Already at the REACH 2018 Communicators' network meeting five such examples, including a project of involving tax offices in disseminating information, had been presented.

Only one NHD had once launched a rather successful public radio campaign. BPR duty holders were reached via a network of laboratories. BPR duty holders are less likely to be organised in associations. Working more with national enforcement authorities (NEAs), Chambers of Commerce, Poison Centres, tax offices and using social media also can help.

NHD correspondents seemed less tempted to replicate ECHA's SME visits programme as they do not envisage the element of staff training as a need, companies are often reserved to cooperate with NHDs as they fear of triggering inspections. The various 'road-shows' and information events that allowed advising companies in one-to-one sessions proved to be more helpful. Such events are conducted in some NHDs attracting at least a half-dozen companies to its weekly one-to-one sessions, most of them being new companies.

8. Data dissemination and engaging companies

The Chair outlined his commitment to ECHA's Management Board to promote awareness for ECHA's public consultations following a suggestion made by the Board members in December 2015. Emphasising the importance of public consultations as a key component of the participatory approach of REACH, Board members recommended an increased role of NHDs in the process.

In HelpNet regular updates, the HelpNet Secretariat already includes information about public consultations. As part of this agenda item, and to strengthen the message, Suzanne WIANDT presented the German RMOA[23] public consultations as a prominent example by which a NHD engages companies in publicly consulting on the risk management of SVHCs.

8.1. Public consultation

Suzanne WIANDT presented the German HD objectives in 'reaching the unreachables' and the experiences gained during targeted awareness campaigns (e.g. post letter campaign sent to 9,000 potential registrants, press relations with chambers of industry and trade, various information material, etc.), with special focus on SMEs and DUs.

She presented the national SVHC consultation procedure giving companies/associations from the affected industries the possibility to submit relevant information to the Federal Office for Chemicals, before risk management options are developed. The relevant information received is sometimes further discussed with the companies affected in face-to-face meetings. Then, the RMOA is developed and published by ECHA and German HDs.

The 'German RMOA-List'[24] is available on the HD website and can be consulted also in English.

8.2. Information on chemicals: Infocards, Brief Profiles and searches

Eoin BRENNAN (ECHA) presented ECHA's new format for informing the general public on chemicals via InfoCards and Brief Profiles. The dissemination tool is designed to summarise the non-confidential data of a substance held in the databases of ECHA, and represents a major step forward in terms of availability of public data on chemical substances.

The presentation guided participants through some hands-on search examples of the

[23] RMOA - risk management option analysis
[24] German RMOA-List:
http://www.reach-clp-biozid-helpdesk.de/de/REACH/SVHC-Roadmap/DE_RMOA-Liste/DE_Stoffliste.html

dissemination pages. The pages offer a single point of access for all information held by ECHA on a specific substance as a whole, rather than substance information under a specific legislative framework.

The starting point for each substance is an easy to understand and general InfoCard ('first tier'), serving as a high-level summary for the general public, consisting of information that is most relevant to an audience of consumers, downstream users and professionals active in the chemical industry.

From the InfoCard, those who are interested can easily navigate to the 'second tier' - the Brief Profile - for more detailed information. From the Brief Profile, users can access the 'third tier', the source information on which the summaries of the InfoCard and Brief Profile are based.

InfoCards are updated regularly and new information is added when available. It was noted that the InfoCards can change as new data is submitted to ECHA.

8.3. Questions & answers session

Due to time constraints the presentations in this section could not be followed by an exchange of views. However, feedback from NHDs will be appreciated at any time.

Closing of the HelpNet Steering Group meeting

The Chair closed the meeting concluding that HelpNet-11 events covered most current and relevant topics on REACH (with a view to 2018 and SME support, public consultations and changes in ECHA's regulatory processes), CLP (pending questions of interpretation and practical implementation) and BPR (hot topics which will be discussed in the following BPR workshop), through presentations as well as breakout discussions. As usual, feedback from participants will be collected over the next few days and the HelpNet Secretariat will be following up the meeting according to an action plan.

He announced the tentative dates for the next HelpNet regulatory workshops following in 2016:

- REACH workshop from 5 to 6 October, in parallel with the Forum 'Training for trainers on the enforcement of exposure scenarios and the extended Safety Data Sheets';

- CLP workshop from 29 to 30 September[25] - dates to be confirmed the workshop is planned to take place back-to back with an event organised by the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.);

- BPR workshop from 1 to 2 September, back-to-back with the Biocides Stakeholders' Day. Due to budget constrains this workshop is still under discussion.

The Chair thanked all correspondents and observers for their active and valuable contribution to the 11th HelpNet Steering Group meeting and invited the BPR members to the following BPR workshop.

9. BPR Workshop

The BPR workshop was co-chaired by Henna PIHA and Nicola TECCE.

The Chair welcomed the BPR correspondents and observers to the BPR workshop and proposed

[25] After the meeting, new dates for the CLP workshop are under discussion: 17 and 18 September 2016.

to switch[26] the order of two agenda points - 9.1 Helpdesk support and 9.2 Update from the Commission - to allow Pierre CHORAINE[27] to present the Commission's update on the BPR implementation and enforcement.

9.1. Helpdesk support: revised approach

Nicola TECCE (ECHA) presented the revised approach for handling BPR questions in HelpEx, based on an analysis of the experience gained with BPR questions since 2013 by the ECHA Secretariat. The analysis demonstrated the need to make better use of all resources involved in the process and proposed a clarified division of responsibilities in accordance with the legal requirements of the BPR. The issue was also addressed in the Competent Authorities' (CAs) meeting of 16 March 2016, in Brussels[28].

Certain issues have arisen during the discussion of such questions in HelpEx resulting in numerous pending (unsolved) questions due to various reasons (e.g. different views expressed by several biocides helpdesks; input needed from the Commission, the Coordination Group or CAs; parallel discussions in various fora).

Nicola TECCE concluded that HelpEx is a useful platform to discuss issues related to the implementation of the BPR, but some questions have to be discussed at a different level. The way forward he proposed to resolve the 'unsolved questions' in HelpEx was:

- National biocides helpdesks continue posting questions in HelpEx which they want to discuss with the other national helpdesks;
- ECHA provides responses on topics which are within its remit;
- For questions that are outside ECHA's remit, the question owner decides on the most appropriate action to be taken (e.g. closure with dissenting views, taken the question forward to a CA meeting, to the Commission or to the Coordination Group);
- HelpEx questions shall be closed with a clear indication of the follow-up action; the final answer is posted in HelpEx after having consulted the question with the most appropriate body;
- FAQs can only touch upon issues which are within ECHA's remit.

The participants agreed to the proposed approach, but requested an opportunity for written feedback on what is to be defined to be in the remit of national BPR helpdesks. Once ECHA receives their feedback, the paper will be provided to the next BPR CA meeting for adoption.

Further, it was clarified that questions received by ECHA from EEA and non-EEA countries will be directed to the appropriate national BPR helpdesks. Also, that questions on 'simplified procedures' shall be added to the list of topics in the remit of NHDs.

The discussion touched upon also the revoked Manual of Decision. It was noted that ECHA is available to provide a link on its website to a folder in S-CIRCABC where the Q&As on scope issues agreed at CA meetings (which didn't go through an Article 3.3 request) can be collected.

During the CA meeting in March, the Commission clearly confirmed that they are not going to create any document replacing the revoked Manual of Decision. ECHA does not have either the remit to manage such guidance.

The issue will be followed up with the Commission in due time. BPR HelpNet members will be

[26] However, the minutes follows the order in the agenda of the meeting.
[27] Pierre CHORAINE joined the event by video connection.
[28] Revised process for handling BPR questions in HelpEx: https://circabc.europa.eu/sd/a/9ae36217-a475-4b95-b77e-dcf73f6d7b40/CA-March16-Doc.7.3%20-%20Revised%20process%20HelpEx.docx

informed accordingly on the decision to make publicly available scope issues.

9.2. Update from the Commission on BPR implementation

Pierre CHORAINE (DG SANTE) presented the Commission's update on the BPR implementation and enforcement, specifically on the following areas: policy papers available on CIRCABC[29]; approval of active substances; product authorisation granted in accordance with the BPR and mutual recognition; treated articles; maximum residue limits in food or feed and the threshold values for determining whether there is a need for a targeted monitoring programme, etc.

On compliance with Article 95 and the deadline of 1 September 2015 - when a biocidal product cannot be made available on the EU market unless either the substance supplier or the product supplier is included in the Article 95 list for the product type - the Commission is actively involved to help companies, developing various guidance - e.g. practical guides for SMEs, guidance on implementation and enforcement - including guidance for in situ generated active substances.

Pierre CHORAINE noted that the Review Programme remains the main priority for Member States, ECHA and the Commission, with an annual target of 50 ECHA opinions and decisions taken by the Commission. He presented the timelines set for Member States to submit the assessment report of the active substances to ECHA and for the ECHA to start the preparation of the opinion depending on the product types.

As regarding the enforcement of the BPR, Pierre CHORAINE sees a strong link between the current established Biocides Enforcement Group (BEG) and ECHA's Forum. The enforcement group discuss how to harmonise national controls at EU level, by sharing experience, identifying tools for information exchange and setting priorities, as for example Article 95 and treated articles.

In his concluding remarks, he mentioned other important areas for the Commission to be focusing on in the future as endocrine disruptors, renewal of rodenticides and the Agency's fees review.

9.3. Questions & answers session

The Commission informed that no regular updates are foreseen for guidance documents. However, the guidance on placing on the market was finalised, and the work on treated articles guidance document is on-going. As regards to BPR and cosmetics, this area remains unclear and there are no plans for the Commission to review the old document.

Commission repealed the Manual of Decisions concerning the old Biocidal Products Directive. Companies who, on the basis of the manual, considered their product to be excluded from the scope of the biocides legislation can contact their national helpdesk to check whether the status has changed. If the product could now fall under the new Biocidal Products Regulation, companies can submit a declaration of interest to notify to ECHA until 3 October 2016[30].

9.4. Support on Article 95

Maia SOKOLOVA (ECHA) presented the current situation of applications for inclusion in the list of active substances suppliers (Article 95 list) and the questions received from companies by

[29] Policy papers on S-CIRCABC: https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

[30] Manual of Decisions for implementation of Directive 98/8/EC concerning the placing on the market of biocidal products: https://circabc.europa.eu/d/a/workspace/SpacesStore/d0155521-069e-4e8c-91cc-126006d32a83/Manual%20of%20decisions%20(obsolete%20as%20of%2001.10.2015

ECHA on this topic. To be noted that after the mutual recognition agreement[31] coming into force on 1 July 2015, authorisation holders can also be located in Switzerland[32].

ECHA is publishing and updating monthly the Article 95 list[33] to include those companies who have made a successful submission of the required information. Additionally, the pending list of companies who have submitted their applications but the assessment has not been finalised yet is updated monthly.

Regarding the Article 95 and the Review Programme, it was mentioned that the Commission and Member States redefined 'active substance' to specify the precursor and in-situ generation system combinations covered. Consequently, the newly redefined entries will replace the old entries in the list of substances in the Review Programme and in the list of Article 95 list, accordingly.

It was clarified that Article 95(4) interpretation implies that letter of access issued for the Article 95 can be further used for the authorisation, unless specifically mentioned otherwise.

9.5. CLP provisions for BPR

Outi TUNNELA (ECHA) presented the CLP provisions for biocidal products and biocidal active substances as well as classification, labelling and packaging provisions under CLP and BPR.

Similarities and differences under the two regulations and specific labelling and packaging cases were discussed, as for example: mixtures contained in small or difficult to label packages, certain hazard classes triggering child-resistant fastening or tactile warnings. Supplemental information can be provided on a separate leaflet for biocidal products (Article 69(2) and (3) of the BPR).

It was concluded that a CLP proposal for an active substance should be timely prepared, in consultation with a CLP expert, taking into account the local risk assessment. Biocidal products are classified, packaged and labelled in accordance with CLP, but in addition need to comply with the approved summary of biocidal product characteristics (SPC) and the Biocidal Products Committee (BPC) opinion.

It was clarified that classification and labelling information will not be a part of the SPC any longer from October 2016 when SPC editor 2.0 will be released. Information on the C&L can be found in the product assessment report (PAR) contained in the R4BP 3 application.

9.6. Same biocidal products regulation and related IT tools

Valerio SPINOSI (ECHA) presented the reviewed Same Biocidal Products Regulation (SBPR) and the related IT tools. The amendment of the SBPR will respond to the needs of companies, in particular SMEs. It will clarify that an application for a same product authorisation can be also submitted at national level where the related reference product has been authorised by the Commission through the Union authorisation procedure.

He outlined the present and future opportunities offered by the new SBPR and the subsequent changes to be implemented in R4BP, particularly allowing links between authorisations granted under different procedures.

ECHA will prepare and submit to the Commission an opinion on the application for same

[31] Agreement between the Swiss Confederation and the European Union on the mutual recognition of conformity assessments:
https://www.swissmedic.ch/ueber/01398/01401/01936/01938/index.html?lang=en
[32] Biocidal products on the webpage of the Swiss Federal Office of Public Health:
http://www.bag.admin.ch/anmeldestelle/13604/13869/index.html?lang=en
[33] List of active substances and suppliers:
http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

product union authorisations and will develop guidelines on the details related to the handling of the applications covered by the SBPR. After having consulted the interested parties, ECHA will also update the users and CA manuals and issue a dedicated chapter of the practical guide.

9.7. Campaign on treated articles IT tools

Valerio SPINOSI (ECHA) presented the campaign on treated articles and introduced the banners[34] available on ECHA website, ready to be used by NHDs and CAs in their own national campaigns.

He then referred to the difference between treated articles and biocidal products and the implementing acts (Article 3.3 of the BPR) issued by the Commission on: anti-viral tissue impregnated with citric acid[35] and horse cover impregnated with permethrin used for the protection of horses and their environment from insects regarded as biocidal products[36].

The participants were reminded of the following fast approaching deadlines:

- 1 September 2016 - for submission of a complete application on the active substances contained in a treated articles which are not yet in the approval process (Review Programme) or already approved or listed in the Annex I of the BPR, and

- March 2017 - from this date onwards only articles treated with a biocidal product containing an active substance that is approved, listed in Annex I, or is under evaluation, can be placed on the EU market.

Closing of the BPR workshop

The Chair thanked all participants for their active and valuable contribution to the workshop and informed that the action list will follow after the meeting.

[34] Treated articles high resolution banner in all EU languages is available on ECHA website, at: http://echa.europa.eu/en/press/image-gallery

[35] Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

[36] Draft Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

Annex I - List of participants

Members of HelpNet

Country	**Members of HelpNet / Advisers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
Austria	LEITNER Stephan			X	X	X	
Austria	WEBER Michael	X		X			X
Belgium	CLAES Kristof		X	X	X	X	
Bulgaria	GAIGUROVA Margarita	X		X			X
Bulgaria	HRISTOVA Viktoriya		X	X			X
Croatia	LOVRIĆ Zdravko		X	X	X		X
Croatia	VRHOVAC FILIPOVIC Ivana			X	X		X
Cyprus	HADJIGEORGIOU Andreas			X	X	X	
Cyprus	ORPHANOU Maria	X		X			X
Cyprus	PALEOMYLITOU Maria		X	X			X
Czech Republic	KATRUSAKOVA Adela		X	X			X
Czech Republic	KOLAR Jan	X		X			X
Czech Republic	KUCERA Tomas			X	X	X	

Country	**Members of HelpNet / Advisers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
Denmark	ANDERSEN Trine Thorup		X	X			
Denmark	JØRGENSEN Anders Skou			X	X	X	
Denmark	DYEKJÆR Sidsel	X		X			X
Estonia	AMELKINA Anna	X		X			X
Estonia	LAHE Aigi		X	X			X
Estonia	ROOP Evelin			X	X	X	
Finland	MATTILA Hannu			X	X	X	
Finland	PRIHA Maarit	X		X			X
Finland	TOLSA Leeni		X	X			
Finland	TUHKUNEN Sari	X		X			X
France	DUFFORT Gaëlle		X	X			X
France	HAYAUD Nathalie	X		X			X
Germany	GÜNNEWIG Kathrin			X	X		
Germany	KNIETSCH Anja		X	X			
Germany	WIANDT Suzanne	X		X			

Country	**Members of HelpNet / Advisers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
Greece	SKAFIDA Panagiota	X		X	X		X
Greece	TSITSIMPIKOU Christina		X	X	X		X
Greece	VAGIAS Vasileios			X	X		
Hungary	BURAI Erika		X	X			X
Hungary	GÖBLYÖS Dávid			X	X	X	
Hungary	NYITRAI Péter Viktor	X		X			X
Ireland	MC GUIRE Patricia				X	X	
Ireland	RODGERS Karen	X		X			X
Ireland	WALSH Caroline		X	X			X
Ireland	WALSH Caroline						X
Italy	D'ILIO Sonia		X	X			X
Italy	GIANNOTTI Francesca	X		X			X
Latvia	BROVKINA Julija			X	X	X	
Latvia	JAUNKALNE Natālija	X		X			X
Latvia	RUBENE Līga		X	X			X

Country	**Members of HelpNet / Advisers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
Lithuania	JANONYTĖ Agnė		X	X			X
Lithuania	PIPIRAITE-VALISKIENE Donata	X		X			X
Lithuania	VZESNIAUSKAITE Evelina			X	X	X	
Luxembourg	CHOCHOIS Laurene		X	X			X
Luxembourg	HERMES Joe			X	X	X	
Netherlands	BEIJ Tatjana Eveline			X	X	X	
Netherlands	Van IERSEL Peter	X	X	X	X	X	X
Netherlands	WOUTERS Margaretha	X	X	X			X
Norway	LARSEN Kristin Ann		X	X			
Norway	TVERMYR Marianne	X		X			X
Poland	CIEŚLA Jacek						X
Poland	DOMAŃSKI Krzysztof		X	X			X
Poland	KAMIŃSKA Renata			X	X	X	
Poland	WASIAK-GROMEK Monika	X		X			X
Portugal	ARAÚJO Fátima de Maria	X		X			X

Country	**Members of HelpNet / Advisers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
Portugal	RAMOS Cesaltina			X	X	X	
Romania	CAROLE Nicoleta		X	X	X		X
Romania	DRAGUSANU Mihaela			X	X	X	
Slovakia	DANIHELOVÁ Martina	X		X			X
Slovakia	PORUBIAK Michal		X	X			X
Slovakia	SKULTETYOVA Maria			X	X	X	
Slovenia	HUMAR JURIČ Tatjana		X	X			X
Slovenia	MENARD SRPČIČ Anja	X		X			X
Slovenia	PAVLIČ ČUK Marta			X	X	X	
Spain	LOPEZ FRANCO Maria Aranzazu			X	X	X	
Spain	SANCHEZ DIAZ Elena Maria		X	X			X
Spain	ZAMORA NAVAS Laura	X		X			X
Sweden	BENGTSSON Helge Leif			X	X	X	
Sweden	KRAMER Helena	X		X			X
Sweden	NORRTHON RISBERG Susanna		X	X			

Country	**Members of HelpNet / Advisers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
United Kingdom	LAU David			X	X	X	
United Kingdom	PEPPIN-HUGHES Lindsay	X		X			X

Country	**Invited Experts**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
Germany	MUEHLE Ulrike					X	X
Germany	SEUBERT Kristof						X
Germany	GÜNNEWIG Kathrin					X	
Germany	WALTHER Thilo					X	

Country / Organisation	**Stakeholders/Observers**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
A.I.S.E.	BERTEIN Caroline		X	X			
A.I.S.E.	KARJOMAA Sari		X				
Federal Office of Public Health	KOLP BUCHS Brunhilde			X	X		
IMA Europe	CARRIER Lara	X		X	X		
Istanbul Minerals and Metals Exporters Association	ÖZGÜN Pinar		X	X	X	X	
Serbia	GRUJIC Jelena	X	X	X	X	X	X
Serbia	RASOVIC Aleksandra	X	X	X	X	X	X
Swiss Notification Authority for Chemicals	BLASER Olivier			X	X	X	

DG	**European Commission** **- by videoconference -**	**REACH workshop** (5/04 pm)	**CLP workshop** (5/04 pm)	**HelpNet Steering Group meeting** (6/04 am)	**BPR workshop** (6/04 pm)	**IT Tools training for BPR Helpdesks** (5/04 pm)	**IT Tools training for REACH and CLP Helpdesks** (5/04 am)
GROW	POPOVA Temenuzhka			X			
SANTE	CHORAINE Pierre			X			

ECHA staff

Communications:

Lindsay JACKSON, Mikko VÄÄNÄNEN

Support, Forum & HelpNet Secretariat:

Johan NOUWEN, Henna PIHA, Tiina MULTASUO, Peter MEGAW, Maciej BARANSKI, Iris BRIAT, Nicola TECCE, Maia SOKOLOVA, Outi TUNNELA, Christina LOUKOU, Olena KRYCHEVSKA, Pedro ROSELLO VILARROIG, Katarina CENDIC, Jeremy HUYGHE, Wanjiru NJOROGE, Viorica NAGHY

Regulatory Affairs:

Jukka MALM

Legal Affairs:

Minna HEIKKILA, Theodora BASMATZI, Nicholas KNIGHT

Registration:

Christel MUSSET, Laura WALIN, Anisa KASARUHO

Dossier submission & PIC :

Kevin POLLARD, Vasileios TSIFOUTIS, Chiara MACCHI, Javier SANCHEZ-SAEZ

Substance ID & Data Sharing:

Jos MOSSINK, Pawel FIGIEL, Bernadette QUINN

Computational Assessment & Dissemination:

Mike RASENBERG, Alberto MARTIN APARICIO, Eoin BRENNAN, François LE GOFF, Hélène MAGAUD, Alexis QUINTANA SÁINZ, Lucia CONTI, Dorota BURCHARD- SOSNOWSKA

Biocides Assessment:

Hugues KENIGSWALD, Valerio SPINOSI, Jan WEBER, Gabriela ALDEA

Classification and Prioritisation:

Elina KARHU, Kirsi MYÖHÄNEN, Telmo Jorge VIEIRA PRAZERES, Gunilla ERICSSON, Jonas NYGREN

Risk Management Implementation:

Matti VAINIO, Kirsi SIHVONEN, Bridget GINNITY, Sotirios KIOKIAS

Evaluation

Guilhem DE SEZE, Eva VALKOVICOVA

Ofelia BERCARU, Lee WALKER, Laurence HOFFSTADT, Frank LE CURIEUX

IT Infrastructure and Support

Orion ANDREWS, Ruben GONZALEZ VIDA, Livia BRIESE

Corporate Services - event assistants and conference operators

Clemencia WIDLUND, Arutnev GONZALEZ YANEZ-PUHAKKA, Anni HONKA, Marco POPOVIC, Ari VALKEINEN, Tommi AALTONEN, Daniel STEVENS

Annex II - Action points

Nr	Action	A.P.	Person responsible	NHD contact	In ECHA	Due date
1.	Ideas for further activities related to communication on Exposure Scenarios & Chemical Safety Report	3.4	NHDs		Bridget GINNITY	
2.	Feedback from NHDs on gathering feedback messages to 2018 registrants	3.6			Laurence HOFFSTADT	
3.	Consult the ECHA legal unit (and possibly COM) on HelpEx 12981 DE to reopen HelpEx question 12981 ('Does limestone which is surface treated with stearic acid have to be registered?') for further discussion	3.7.2	ECHA NHD	Suzanne WIANDT Claus HAAS	Christina LOUKOU Pawel FIGIEL	
4.	Correspondents to comment on the topics they did not participate during the break-out groups (CLP workshop).	4.4	NHDs		Outi Tunnela	19 April 2016
5.	DE to reopen discussion on 'Contact details of the supplier in SDS'	4.7.2	DE Anja KNIETSCH		Outi TUNNELA	CARACAL meeting in June
6.	Create a HelpEx question about a two-component laundry gel cap.	4.7.2	HU	Erika BURAI		29 April 2016

Nr	Action	A.P.	Person responsible	NHD contact	In ECHA	Due date
7.	Setting e-mail notifications (alerts) on the FAQ platform of HelpEx	5.4	NHDs		HelpNet Secretariat	Ongoing
8.	Comments on the draft Report on NHD 2015 activities Volunteers for the establishment of a HelpNet "Sounding Board" group to support the long term planning of HelpNet activities	5.6	NHDs		HelpNet Secretariat	29 April 2016 (initial, deadline) New deadline to volunteer: 14 May 2016
9.	Feedback on 'BPR questions in the remit of ECHA and NHDs' – annex to be included in the CA paper on the revised process for handling BPR questions in HelpEx. The paper will be finalised for the CA meeting in June.	9.1	NHDs		Nicola TECCE	Done 29 April 2016
10.	Owners of the 'unsolved issues' in HelpEx to set the status of the questions as 'closed' and indicate the action to take (in accordance with the line indicated in the paper).	9.1	NHDs		Nicola TECCE	Ongoing