



Minutes of the 12th HelpNet Steering Group meeting, Regulatory Workshops and IT Tools Training sessions

Time: From 21 to 22 March 2017 **Place:** ECHA Conference Centre, 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.

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1. IT Tools training for REACH and CLP helpdesks

Pedro ROSELLÓ VILARROIG (ECHA) opened the IT tools training welcoming the representatives of REACH and CLP national helpdesks, observers and introducing the four sessions of the training: IUCLID inquiry dossier, REACH-IT online dossiers, Chesar, IUCLID cloud.

The event started with a presentation by **Margot MÄGI** on the IUCLID inquiry dossier followed by a practical exercise. The attendants received a substance data set for an inquiry dossier. When running the validation assistant the companies were required to correct some business rules that were failing.

Alexis QUINTANA-SÁINZ gave a short introduction to the REACH-IT functionalities and an overview of the creation of a IUCLID dossier online, directly from REACH-IT. The members of HelpNet had then the possibility to create themselves an online dossier directly in REACH-IT.

Roberta BERNASCONI gave an introduction to the machinery developed to support the safety assessment and communication of conditions of use in the supply chain. The focus of the presentation was on the tools available for supporting it. In particular, focus was given to the DNEL calculator that now is available in IUCLID, the use map concept and the ESCom phrase catalogue and finally ECHA's Chemical Safety Assessment and Reporting tool (Chesar).

Tommy Hägg presented the newest addition to the ECHA IT tools, the ECHA Cloud Services. This year, ECHA will release a cloud version of IUCLID in order to help smaller companies achieve their goals for the 2018 registration deadline. The IUCLID Cloud application complements the IUCLID application by being adapted to run in a browser. It will significally reduce the technical burden and related costs related to hosting, updating and operating IUCLID locally for industry. In the beginning of April, ECHA will launch the IUCLID Cloud Trial and invite SMEs to try out the service. Users will be able to start and manage the service, import and view substance, mixture and dossier datasets and launch the IUCLID Cloud client to edit datasets.

Later in the summer, ECHA will launch the IUCLID Cloud for SMEs, which allows SME users to prepare their REACH registration dossiers. At the end of the year, ECHA aims to have an improved IUCLID Cloud for SMEs service where creating a registration dossier is actually easier than with the traditional IUCLID application.

HelpNet members had been asked to send to the Secretariat or bring to the meeting IT tools (REACH-IT and IUCLID) related questions they have received recently from their customers and that, either they are confident in replying or that they would like to be able to reply to in the future. However, due to time constraints, this session did not not take place.

2. IT Tools training for BPR helpdesks

In the first part of the training **Francois LE GOFF** and the IUCLID team provided a hands on training on IUCLID for Biocides. An introductory presentation on IUCLID 6 was presented, then a practical exercise was run, supporting the audience to perform an amendment on the content of an active substance IUCLID file.

In the second part of the training **Roberto GILIOLI** provided a basic introduction of the principles and main processes supported by R4BP 3, with a special focus on national authorisation major change and application for same biocidal product. An introduction on the features of the SPC editor was provided, including a description of the new structure of the SPC supporting biocidal product families. Opportunity of questions and answers was given.

Then, in the second part of the training, a case study was presented, providing a practical demonstration on how to use R4BP 3 to perform an application for a same biocidal product

characterised by professional and public use and concentration of a rodenticide active substance of 50 ppm. An application for a major change of a product was performed, with the objective of showing how to apply for reducing the concentration of the active substance in the product from 50 ppm to 25 ppm in order to make it usable for public consumers only.

The questions asked by the audience, were mainly related to user interface and product search features.

3. REACH Workshop

3.1 Company size verification - IT and financial perspective

The Chair invited the participants of the REACH Workshop to address their questions on the presentation `SME definition and benefits under REACH' and `SME Verification'.

The Commission Regulation on REACH fees and charges provides for reductions in fees for companies qualifying for the EU definition of a micro, small or medium company. Companies declare their company size already when signing up in REACH-IT and re-confirm their size again when submitting a registration.

John WICKHAM and Remus CIOATA (Financial unit) and Alexis QUINTANA-SAINZ, Vasileios TSIFOUTIS and Javier SANCHEZ-SAEZ (Registration Unit) were in the room to reply to questions, and provide a live demonstration of the tool.

Remus CIOATA explained that the latest release of REACH-IT provides additional guidance for registrants in self-assessing the size of their companies and uploading the supporting documents in REACH-IT, at the time of submission of a registration. Information in REACH-IT is translated in all EU languages.

During the previous SME verification procedure, one of the challenging tasks for both ECHA and industry was to get access to the supporting documents required in assessing the size of the company, at the submission date. Now, with the new feature in REACH-IT, documentary evidence supporting the declared size category is submitted with the registration dossier.

Alexis QUINTANA-SAINZ made a **live demonstration** of the 'size verification' feature in REACH-IT. He created an account for the registrant, and updated the size of the company – which by default is 'large' in REACH-IT – to 'small'. Then, he went through the supporting checklist provided within the tool and helping the registrant to check if he is entitled for to SME fee reductions; finally, he showed the audience how to upload the supporting documents. More information is available on the ECHA website, at: https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-reach-and-clp

In case the SME verification done by ECHA results in the finding that the size category of the company is larger than the one indicated at the time of the submission an administrative charge will be levied. In addition, the company will be invoiced the balance to the full fees that correspond to the correct company size category for all submission covered by the SME verification procedure. In case the invoice for the balance to the full fee is not paid within the deadlines, this will result in the revocation of the original registration decision assigning a registration number. The use of the initially assigned registration number would no longer be allowed.

NHDs stressed that they do not receive questions on this subject. However, they now feel more prepared to provide guidance to companies requesting information on the SME verification procedure in REACH-IT.

3.2 Annual evaluation report

Ulla HELMINEN (ECHA), chief editor of the report, presented the main findings of ECHA's evaluation activities in 2016 and key messages resulting from the report¹. The annual evaluation report covers evaluation activities and other measures to improve data quality, has recommendations for registrants, and was published in February 2017 on ECHA's website².

In 2016, ECHA focused its dossier evaluation activities on substances with the greatest potential to negatively affect people and the environment: substances produced in high volumes – over 100 tonnes per year – and with a potential concern.

ECHA has taken an integrated strategic approach to target the regulatory activity on substances of potential concern. The evaluation report shows that crucial data is still missing for most substances subject to compliance check. Thus, several additional measures to enhance dossier quality were taken, for example:

- One substance, one registration (OSOR) principle;
- Enhanced completeness check (TCC);
- Substance identity profile (SIP);
- Sectoral approach;
- Letter campaigns;
- Article 36 of REACH;
- Transparency regarding content and target of ECHA's decisions.

To encourage registrants to update their dossiers already before compliance checks or risk management actions take place, ECHA sent letters to the registrants of 270 substances of potential concern, highlighting the deficiencies in their dossiers. The Agency also regularly published a list of substances that may be chosen for compliance checks.

The registration process, in particular the completeness check, was revised to improve the availability of high-quality information in the incoming registrations – both on new ones or existing ones. It now includes manual checks for information that cannot be automatically assessed, ensuring that all information intended by REACH has been included in the dossier. If the companies do not react by the deadline stipulated by ECHA, their registration will be revoked.

In 2016, 184 new compliance checks were concluded, resulting in 169 draft decisions and 805 information requests, of which 550 addressing higher-tier human health and environmental endpoints. This would lead in receiving around 800 pieces of information and helping in deciding of further risk management measures are needed. 152 decisions were adopted containing 597 standard information requests. Regarding testing proposals, ECHA adopted 116 decisions with 260 requests.

On substance evaluation, ECHA adopted the 2016-2018 CoRAP, consisting of 138 substances of which 39 were scheduled for evaluation in 2016 and 20 substance evaluation conclusions published.

Ulla HELMINEN highlighted the recommendations to registrants in the report. Companies shall take stock of these recommendations and update their dossiers especially when their substance is shortlisted for regulatory action. Authorities need the data to conclude whether further risk management is required on these substances:

² Important safety information on chemicals still missing: <u>https://echa.europa.eu/-/important-safety-information-on-chemicals-still-missing</u>

¹ Evaluation under REACH Progress Report 2016:

https://echa.europa.eu/documents/10162/13628/evaluation report 2016 en.pdf/f43e244f-7c90-75bde1b2-3771bcb1f8e8

- Ensure the safe use of the registered substance by keeping the dossier updated;
- Exposure assessment and risk characterisation must cover all hazards;
- Familiarise with the REACH requirements for skin corrosion or skin irritation, serious eye damage or eye irritation, acute dermal toxicity and skin sensitisation;
- Use the validation assistant plugin for IUCLID when preparing a registration dossier;
- Allow the publication of the name of the lead registrant on ECHA website, when forming a joint submission;
- Provide clear information on the substance identification profile (SIP);
- Before using any of the test methods, consider whether the method is adequate for the intended regulatory purpose; the test method regulation was amended and the new provisions came into force in March 2016 and is applicable under REACH Article 13(3);
- All physico-chemical hazards testing should be tested according to the methods set out in the CLP Regulation; ECHA's Guidance on Information Requirements and Chemical Safety Assessment³ has been updated to clarify this requirement.

The executive summary and the recommendations to registrants were translated into 23 EUlanguages and NHDs are invited to share this information in their networks, in their national languages. Translations are available on ECHA's webpages⁴.

Question:

Following the amendment of Annexes VIII, IX and X to the REACH Regulation, the extended one-generation reproductive toxicity study (EOGRTS) was incorporated in the REACH information requirements in March 2015. Also, the guidance document on EOGRTS was updated.

What are the experiences with the EOGRTS since then?

Answer:

Indeed, ECHA started to address the EOGRTS information requirement in the evaluation of dossiers and EOGRTS studies have been requested both under testing proposal examination and compliance checks. Some earlier testing proposals are currently with the Commission for decision making, but are foreseen to be re-submitted as testing proposals to ECHA later this year or in early 2018.

A technical report regarding the extended one-generation reproductive toxicity study design was published on ECHA webpage in September 2016 and the recommendation for registrants to familiarise with the document is part of the 2016 Evaluation report.

3.3 Enhanced completeness check

Margot MÄGI (ECHA) presented the enhanced **Technical Completeness Check (TCC)**, the state of play of last year's changes and the impact on REACH registration dossiers so far.

ECHA discussed the concept of enhanced TCC and assessed possible actions to further address SID deficiencies in individual dossiers in consultation with the Management Board, Member States, CARACAL, European Commission and industry associations.

On 21 June 2016, ECHA launched the enhanced completeness check based on experience from the first two registration deadlines and about 40 000 dossiers.

³ Guidance on IR & CSA, Chapter R.7a Endpoint specific guidance (version 5.0, December 2016): <u>https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f</u>

⁴ ECHA plans and reports: <u>https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports</u>

ECHA automatically performs a manual verification⁵ to all new and updated dossiers. Manual checks were introduced to verify those elements that could not be automatically checked, ensuring that registrants who deviate from standard requirements provide a justification that is relevant within the REACH context (Article 20 of the REACH Regulation). The areas for manual checks are substance identification, data waivers, chemical safety report and testing proposals on vertebrate animals.

The enhanced TCC also relates to reviews of legal requirements/interpretations - EOGRTS; second species for pre-natal development toxicity study; skin and eye irritation, tiered approach; testing proposals to document alternative methods - enhancement of the OSOR principle and improved IUCLID format.

Quantitative and qualitative observations⁶ from the first half year of applied enhanced TCC show the extra work involved, but is considered a worthwhile investment to enhance the availability and transparency of the data in the existing registration dossiers.

Companies can still check if their registration dossier contains all necessary information by running the IUCLID Validation assistant. However, she reminded that ECHA staff will also do a further manual check to see that data is relevant within the context of REACH. These manual checks apply equally to initial registrations and updates and cannot be replicated by the Validation assistant.

Margot MÄGI invited participants to raise awareness among their customers and promote the document 'Information on manual verification at completeness check', the TCC letter and the forthcoming webinar on completeness check'⁷.

Question:

Are registration dossiers picked up for the manual check in a percentage of 33% always?

Answer:

On average, 67% of the registration dossiers were found adequate according to ECHA verification systems, that is why the remaining 33% were subject to the manual verification.

3.4 Taking action on existing registrations

István MÁK (ECHA) presented the actions undertaken by ECHA on existing registration dossiers, ensuring that registrations are up to the expected standard.

As presented under the previous agenda item, ECHA launched the enhanced TCC in June 2016. Since then, TCC has been applied automatically to all new and updated dossiers. However, a large number of the existing dossiers are rarely updated (~60% have never been updated); even most of the updated registration dossiers have been updated only once throughout their life. Therefore, in the interest of fairness between registrants, ECHA have introduced the R-TCC, checking in more detail the completeness of existing registration dossiers.

The R-TCC aims to bring existing registration dossiers to an equal level of completeness, making sure they contain the information that the law requires. This approach is supported also by the Board of Appeal (BoA) decision of March 2016 (case A-022-2). R-TCC guarantees that registrations dossiers contain all data elements required by REACH as input for the evaluation and risk management processes

Following two pilot ECHA campaigns in July and November 2016, ECHA wrote to companies

⁵ Information on manual verification at completeness check:

https://echa.europa.eu/documents/10162/13652/manual completeness check en.pdf ⁶Enhanced completeness check delivers its first results:

https://echa.europa.eu/-/enhanced-completeness-check-delivers-its-first-results

⁷ Webinars: <u>https://echa.europa.eu/support/training-material/webinars</u>

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who had provided data waivers for hazard data stating that the study was not ready. In total, ECHA requested information for more than 140 endpoints from 39 registrations for 24 substances. By the November deadline, almost all of the registrations (37 out of 39) had been updated. Registration decisions for the two registrations that were not updated have been revoked, meaning that those companies can no longer legally manufacture or import the substances in the European Union.

The results of the 2016 campaigns show that R-TCC can be successfully used to target registration dossiers that are not otherwise updated, and align them with the current TCC standard.

The Implementing Regulation on joint submission of data and data sharing⁸ gives ECHA the mandate to make sure that all registrants of the same substance are part of one joint registration. In case of the dispute, if registrants cannot find an agreement on the sharing and joint submission of data, the potential registrant can file a dispute with ECHA as a last resort. ECHA can then provide a token to access the joint submission.

For registration dossiers submitted in the past and not part of a JS, ECHA is contacting the companies who breached this obligation when submitting their dossiers. They are asked to bring themselves in line with the JS obligation within a period of 6 months. Those who have not agreed on forming a JS will have their registration number revoked. Meanwhile intermediate registrations and NONS (400 numbers) are deprioritised and will be dealt with at a later stage.

István MÁK then presented the so called '**false lead cases'**, a project started in May 2016, when in the TCC step ECHA found 50 empty dossiers with the statement that the dossier will be updated when data is available; most of these dossiers were submitted well in advance of the registration deadline, and are so called 'manifestly incomplete lead dossiers'. One specific company submitted most of the dossiers, presumably as a placeholder for future submissions, without having agreed either their leadership or the dossier content with the SIEF members, and blocking the lead role.

In these cases, ECHA sent communication to all pre-registrants of the substances (~4800 letters) in June and September 2016. Since then, ECHA received 224 replies from companies and in 14 cases, there is evidence that the current lead was not elected and supported by the rest of the SIEF. In eight cases of these registrations, ECHA took action and will soon transfer the lead role. For the other registrations, ECHA did not receive evidence from the SIEF members that there is an agreed lead registrant in place.

István MÁK concluded that the R-TCC strategy guarantees that registrations dossiers contain all data elements required by REACH and a better input will be provided for the evaluation and risk management processes.

Question:

In the absence of new registrants joining an existing SIEF, refund of their existing registrants who paid for the registration is not possible?

Answer:

Indeed, if there are no new registrants joining the JS, there is no possibility for refunds, and the price of the letter of access remains high/unchanged.

⁸ Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 (REACH): <u>http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN</u>

3.5 Break-out groups - ECHA and national helpdesks preparing for the 2018 REACH registration deadline

3.5.1 Preparations for the 2018 REACH registration deadline

HelpNet members discussed about preparations for the 2018 REACH registration deadline:

a) ECHA and NHDs working together for REACH 2018 deadline related questions

- The NHDs found the IT training of the morning session useful. Some even mentioned that it will help them replying to companies' questions.
- Nevertheless, companies seem to have realised that NHDs reply to regulatory questions and ECHA to IT tool related questions. Therefore, NHDs do not see many IT tools questions.
- In general, still very little activity regarding REACH 2018 related questions. Mostly from downstream industries concerned about their substances.
- Better communication needed (on behalf of NHDs, maybe also by ECHA) to make it clear that NHDs cannot reply to process related questions.
- As most REACH-IT related questions are expected to be related to specific submission, providing a test environment for NHDs would not enable them to help better.
- ECHA could nevertheless produce material on REACH-IT for NHDs explaining/illustrating the registrants' workflow in the system (documents with screenshots, webinars, and videos), which would allow them to understand better their customers' situations.
- Concluded that other REACH-IT support material which ECHA can prepare with considerably less resources would be the option to pursue.
- NHDs would like to see in the next meeting (WebEx planned in July) ECHA support plans for 2018 registrants, to discuss and conclude the NHD role in the picture.
- NHDs have a resource issue: In many countries no extra resources for the deadline are currently foreseen. Intervention at the high level was found necessary.

b) Exchanging information on registration progress

Lists of pre-registrants and registrants have been sent to competent authorities (CAs) via REACH-IT in May 2016 and January 2017. ECHA offered CAs the lists as a mean to support them in gaining a better insight about the 2018 deadline registration state-of-play in their countries.

The UK and ES colleagues have effectively used the lists. The ES colleagues have made a thorough analysis of the registration situation in Spain, the UK colleagues have used the lists to identify 'vulnerable' pre-registrants based on the following criteria:

- SME
- No prior registration experience
- No pre-registrations for previous deadlines
- Fewer than 20 pre-registrations for 2018

UK has also identified 'grey' companies, based on the following criteria: dissolved, closed, no longer trading, unreliable company data.

The participants discussed the usefulness of the lists and whether the creation of a dynamic network of CAs exchanging registration information/data with ECHA and between each other could be beneficial to monitor the registration progress and target vulnerable registrants. The following feedback was gathered:

- Registration lists provided by ECHA are very useful and helpful for monitoring purposes.
- Time saved compared to searching data in REACH-IT.
- Lists help identifying 'vulnerable' companies and contacting those companies for which a lead registrant has not been identified for their substance.
- The lists help developing concrete strategies for targeting the registrants with proper support.
- Exchanging information between ECHA and CAs is useful for monitoring the registration progress at a national and EU level.
- It is beneficial to provide CAs with the possibility to exchange monitoring and data analysis tools between each-other (via WebEx, for example).

3.5.2 Questions national helpdesks expect in 2018

Pedro ROSELLÓ VILARROIG (ECHA) took the floor on behalf of Germany and presented the questions collected from the joint series of events organised by the German helpdesk with various chambers of industry and commerce (IHK) in 2016. The events aimed to inform companies, especially SMEs about the 2018 registration of chemicals under the REACH regulation. The German helpdesk has compiled the frequently asked questions from these events and published them on its website⁹.

A number of questions were discussed in order to align the views of the different NHDs. Participants discussed how the HelpNet can work more efficiently and closer towards the 2018 registration deadline. The three elements were the use of HelpEx; structure and content of the upcoming HelpNet workshop and a proposal for a leaner FAQ creation process. Due to time constraints the discussion will have to be continued by means of a survey.

The presentation went on to discuss a number of frequently received questions.

Issue 1: **REACH registration avoidance possibilities**. There was a general consensus that the quantities per year calculated are based on the average production or import volumes for the three preceding calendar years, even after the pre-registration period is over. This resulted in the following scenarios:

Scenario 1: Manufacture/Import (M/I) is stopped entirely. No obligation to register due to the change of role to downstream user.

Scenario 2: M/I is reduced (below one ton per year). As it was above the previous years then a registration obligation remains.

Issue 2: **Substance ID/impurities/data requirements**. In case of natural substances versus artificially created substances the consensus was that the chemical analysis is not sufficient to decide if imported substance meets the definition of a natural substance. Other factors have to be considered.

Issue 3: **Joint Submission/SIEF/data and cost sharing**. The next question was about whether data has to be obtained from data holder that is not required for the registration itself but rather for the classification. Participants expressed a common understanding that the known results must be taken into account (unless the opposite can be proven), but the data access does not need to be purchased, when the study is not part of the information

⁹ IHK-Veranstaltungsreihe REACH 2018 - Jetzt erfolgreichregister registrieren!: <u>http://www.baua.de/de/Publikationen/Fachbeitraege/REACH-2018.pdf</u>

requirements (e.g. for tonnage 1-10t).

Issue 4: Exemptions Recycling. The process of molten zinc to zinc can be considered as manufacture under REACH when it is recovered from waste. Under Article 2(7)(d) this can be exempted from registrations if the conditions for the exemptions are met.

Issue 5: Non-EU manufacturer. It was agreed that a non EU entity can only appoint one Only Representative. Difficulties of the enforcement were discussed. Higher information requirements cannot be avoided by appointing multiple ORs.

Issue 6: Brexit/Loss of lead registrant. The UK's withdrawal from the EU had not been triggered at the time of the discussion. It was stated clearly that an existing registration cannot be transferred without an actual asset transfer. Only in those cases can the registration be transferred. All related Brexit issues may change during the upcoming withdrawal negotiations.

Pedro ROSELLÓ VILARROIG took the opportunity to raise three questions to the participants, in view of the upcoming registration deadline and the need to strengthen the communication and cooperation amongst the HelpNet correspondents. General discussion about the FAQ process that will become leaner and quicker in the future. This was generally appreciated by the participants.

3.6 Update on unsolved HelpEx questions

On behalf of the German helpdesk, **Pedro ROSELLÓ VILARROIG** introduced the following unsolved/open questions posted by them in HelpEx:

HelpEx ID 13926 (current status: unsolved): Is an adhesive tape an article or a carrier with a substance/mixture?

HelpEx ID13937 (current status: unsolved): Is the use of the substance in in-vitro diagnostics covered by the exemption according to article 56(3) (Use of an Annex XIV substance in scientific research and development?

HelpEx ID 13821 (current status: open): Is a metal band which is coated with a superconducting substance an article or a carrier with a substance? The question is timed out. Only DE and ECHA commented on this question.

ECHA had provided feedback to DE on these HelpEx questions. In the absence of the German correspondent or the intervention of any other correspondent, and as the first two questions were closed for comments (status 'unsolved'), NHDs were invited to provide their feedback to DE or the HelpNet Secretariat.

4. CLP Workshop

Outi TUNNELA (ECHA), the Chair, welcomed the CLP correspondents and observers participating to the CLP Workshop organised during the 12th HelpNet Steering Group meeting and the 10th anniversary of REHCORN-HelpNet.

4.1 Update on actions from CLP workshops in 2016

The Chair summarised the actions taken after previous HelpNet CLP Workshops in April and October 2016.

(1) Classification and labelling related to terms "form" and "use": the topic will be discussed during the break-out group session (see point 4.4).

(2) The additivity principle for constituents with similar modes of action: the discussion at CARACAL is concluded and the relevant interpretations are included in the on-going update of the Guidance on the CLP criteria.

(3) Classification and labelling of e-liquids (HelpEx 14020): an FAQ proposal was prepared. The first round just ended (on 15th March). A new draft and the second round will follow after the comments and feedback have been taken into account.

(4) Classification and labelling of mixtures contained in soluble packaging with multiple compartments: a suggestion was presented in October 2016. Due to challenges in finding a common agreement, the document on 'soluble packaging – C&L' was compiled and provided to the participants (CIRCABC) for further discussion. The topic will be discussed during the break-out group session (see point 4.4).

(5) Labelling of articles acting as containers (e.g. pens) (HelpEx 14021): the FAQ is in the process. The writing instruments industry has already contacted the Commission regarding the outcome of the discussion. The topic of labelling of writing instruments is foreseen to be discussed during the CARACAL meeting in June.

(6) A request to the NHD to insert in HelpEx any cases they may have encountered regarding the problematics of SCLs higher than the GCL was made in October. So far, there has been no input, so the request was now repeated.

(7) Bridging principles were under discussion during the CLP workshop in April 2016. Thereafter, discussion continued between the COM and ECHA. There are still many open issues which are foreseen to be continued in a subgroup. There will be a request to MS to nominate experts to such a subgroup in the on-going CARACAL.

4.2 The consequences of new Annex VIII

Introduction to the Poison Centre's project

Daniel SOMPOLSKI (ECHA), working on the Poison Centre's project in ECHA, highlighted the main effects of the new CLP Annex VIII: ECHA's responsibilities, timelines and the next steps for industry, appointed bodies and poison centres and ECHA. The aim of the project is to guarantee the same level for emergency health response around Europe.

The new Annex VIII on **harmonised information relating to emergency health response** is expected to be published within the next few days. All the needed tools are to be finalised in 2017, guidance and support material in 2018. Thus, the format and editor tools, UFI generator (unique formula identifier), guidance and support material will be available in 2019. The notification process is to begin in January 2020.

Daniel SOMPOLSKI presented an overview of the forthcoming **notification process** from the point of view of all the actors in the chain. Importers and downstream users placing mixtures

on the market will submit notifications through PCN (Poison Centres Notification) portal on mixtures for consumer use, professional use and industrial use within certain steps (from 1st January 2020, 2021, 2024, respectively). ECHA will launch a feasibility study this spring. Q&As will be provided on ECHA's website based on received feedback.

The participants of the workshop raised some questions/points to be taken into account, such as relabelling of products, the length of codes, avoiding duplication of UFI numbers. Further questions were encouraged during the evening reception.

4.3 Application of CLP criteria to nanomaterials

Ari KARJALAINEN (ECHA) updated on the state of play concerning nanomaterials and the CLP Regulation.

Currently, there is **no harmonised classification** in Annex VI to CLP specifically for a nanomaterial form of any substance. However, the CLP Regulation recognises different forms of a substance or mixture. The impact of nano forms on the hazardous properties needs to be considered for classification and labelling. The C&L inventory includes some substances with self-classification as nanomaterial. At the level of the United Nations, discussion is ongoing about the applicability of GHS to the classification of nanomaterials.

Ari KARJALAINEN also presented an overview of **a general CLH process** in the form of an example, an ongoing process: the first CLH dossier (TiO₂), which includes a nanomaterial form. After more than 500 comments received during the public consultation phase, the opinion development is ongoing. The RAC discussion is expected this year.

4.4 Break-out groups

4.4.1 C&L according to form/state

Jonas FALK (SE) introduced the forthcoming discussion. He questioned the practical meaning of the wording in e.g. Article 9(5) CLP: 'When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.'

It was agreed in the previous workshop in October 2016 that the topic must be further discussed and that there may be a need to check if there is a need to improve the current wording in the Guidance on the CLP Criteria on reasonably foreseeable use. The outcome of the discussion is provided in the Annex I.

4.4.2 Use of the REACH data and classification

Caroline WALSH (IE) outlined issues to be discussed: permissions to use data from a registration dossier, reliability of data, is it possible to derive a classification based on REACH data (WoE), differences between REACH and CLP guidance, test methods used. The outcome of the discussion is provided in the Annex I.

How to deal with the classification and labelling of mixtures in soluble packaging

Outi TUNNELA (ECHA) presented the background for discussion. The distributed follow-up paper includes the legal framework and reasons for concern. The question is 'how should products in soluble packaging with multiple compartments be classified and labelled?'. The outcome of the discussion is provided in Annex I.

4.5 Timed-out CLP questions

The following timed-out questions were asked to be closed:

- HelpEx 12580 (owner of the question: PT)
- HelpEx 13915 (owner of the question: SE)

The former cannot be entirely solved, but will be obsolete on 1 June 2017. The latter will be closed with a mention that the issue should be taken up at GHS.

4.6 Update on unsolved HelpEx questions

Outi TUNNELA (ECHA) presented the three unsolved CLP questions:

- HelpEx 12322
- HelpEx 12323
- HelpEx 12368

The owners of the questions will check if the current draft guidance on labelling already covers the identified problematics.

Closing the CLP Workshop

The Chair closed the CLP Workshop and invited the participants to the reception of the 10^{th} anniversary of the REHCORN - HelpNet.

10 years of REHCORN¹⁰/HelpNet

On 21 and 22 of March 2017, the HelpNet celebrated its 10 years of work and efforts to provide consistent and harmonised advice on chemicals legislation across the European Economic Area. Advice that companies need to be able to comply with the demanding requirements of REACH, CLP.

The Executive Director of ECHA, Geert DANCET addressed the participants, the contributors from ECHA and the colleagues that at some point have been part of the HelpNet. He praised the devotion and hard work of all the members, and encouraged all to strengthen cooperation and commitment. HelpNet has a common goal next year to help companies in fulfilling their registration obligations under REACH. The HelpNet is here to help companies ensure that chemicals are used and handled in a safe manner, that humans and the environment are adequately protected, that chemicals can be freely marketed in Europe, and that the European chemical industry keeps up in the innovation race. This is an ambitious vision and a big task, but well worth striving for.



¹⁰ REHCORN stood for **<u>RE</u>**ACH <u>H</u>elpdesk <u>**Cor**</u>respondents <u>**N**</u>etwork. When the CLP helpdesks joined the network, it was re-named as the network of REACH and CLP Helpdesks (HelpNet). As the BPR was already in our minds we have decided not to further specify for which regulations we would work together

5. The 12th HelpNet Steering Group meeting

5.1 Welcome by Andreas Herdina

Andreas Herdina (ECHA), the Chair of HelpNet, opened the 12th HelpNet Steering Group meeting by welcoming the REACH, CLP and BPR national helpdesks (NHDs), representatives of the European Commission, observers from candidate countries and industry. Also, Kevin HOBAN from the Only Representative Organisation (ORO) and Tiine CATOOR (invited speaker).

The names of all participants attending the 12th HelpNet Steering Group meeting, regulatory workshops and the IT tools training sessions are listed in Annex V of these minutes.

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

The Chair introduced the revised HelpNet 12 agenda. Without further changes, the agenda of the meeting was approved. 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.

The Chair informed that the minutes of the 11th HelpNet meeting - including the Steering Group meeting, IT tools training sessions and the regulatory workshops - were approved by written procedures and published on the ECHA website and S-CIRCABC. He also mentioned that all HelpNet 11 action points were closed, with no exceptions.

5.3 Introducing SliDo

Olena KRYCHEVSKA (ECHA) introduced SliDo, a new engaging environment offered by ECHA, allowing participants to join in easily from any device¹¹, ask questions during the meeting, vote the questions they liked the most and answer polls prepared by the HelpNet Secretariat. The platform will be used for future HelpNet events if found useful. It enables both online and onsite participants to interact in real-time, increases level of participation, allows simultaneous statistics and feedback. The results of the polls are presented in Annex IV.

5.4 National helpdesks activities 2016

The Chair thanked the HelpNet correspondents for their reports on past and future activities¹².

He presented the number of enquiries received by NHDs in 2016, the general trends and availability of resources. Once again, a high proportion of BPR related questions were reported by national helpdesks, replicating the experience of the ECHA Regulatory Advice Team.

To get a better understanding for the wide disparity in numbers of questions received by national helpdesks, the HelpNet Secretariat used the SliDo tool and asked participants why do they think the number of questions received by their NHD is above or below the HelpNet average? Respondents to SliDo mostly referred to the small or large size of their country, market, and/or chemicals sector when explaining the deviations from the average. Responses received during the meeting will be reflected in NHDs 2016 activities report.

In 2016, NHDs have organised events and awareness raising activities on various topics13 and

¹¹ Through three easy steps: open browser, navigate to http://slido.com and join the event code (HN12) ¹² Four reports – one CLP and three BPR - are missing, thus not taken into account in the graph presented on the total number of enquiries received by the NHDs in 2016

¹³ REACH 2018 registration, data sharing, SDS/eSDS, communication in the supply chain; CLP: Art. 45 (submission of information to the poison centres), classification & labelling, especially of mixtures; BPR: authorisation of biocidal products, labelling, and professional use.

have planned more events targeted to the REACH 2018 registration deadline. NHDs planning to invite an ECHA speaker to their event, were asked to submit their request in due time, through the contact form available on ECHA's website¹⁴.

Related to upcoming REACH 2018 events, ECHA have drawn up a calendar of events around Europe, focusing on the 2018 deadline. If NHDs have interesting events to promote they are invited to send the details of the event to ECHA¹⁵.

Regarding new ways to support companies, about half of the NHDs identified more efficiently by: improving the structure and the content of their webpages, organising topical workshops, face-to-face meetings, participating in industry events, translating or promoting ECHA's publications and webinars (e.g. providing subtitles in local languages).

The national reports also contain suggestions for ECHA and HelpNet for further improvements in relation to the identified hot topics, for example: translations of FAQs, Q&As, manuals and guidance documents, IT tools training and webinars.

The draft report on national helpdesks activities 2016 will be available on S-CIRCABC after the meeting for fact checking and possible comments.

5.5 New observer: Only Representative Organisation

The Chair invited **Kevin HOBAN** from the Only Representative Organisation (ORO) to present the activities related to REACH and the support given to industry, including SMEs. ORO is an accredited stakeholder organisation of ECHA¹⁶ since December 2011 and has played an active role in various forums since that time.

Kevin HOBAN, Treasurer of ORO, presented the services provided by his organisation to non-Community manufacturers and EU based importers. ORO represents the majority of Only Representatives (ORs) service providers in Europe, and it will celebrate 10 years of service next year.

ORO's main objectives are to set up OR guidance and quality standards, develop a common understanding of REACH requirements for ORs, represent the interests of ORs and non-EU manufacturers, cooperate with regulators and other stakeholders in the REACH process and protect non-EU manufacturers from discrimination through REACH and EU against WTO¹⁷ claims.

ORO promotes the good reputation of ORs, generally through proper behaviour, active communications with parties and professional execution of services and actively strive to work in accordance with the ORO Best Practice Guide¹⁸.

HelpNet members agreed to the participation of ORO as an observer of the HelpNet Steering Group as well as any forthcoming HelpNet regulatory workshops and other HelpNet activities. Kevin HOBAN expressed his appreciation for the opportunity given to ORO to participate in the work of HelpNet and committed to support the HelpNet activities as best they can.

https://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-

¹⁴ Contact form: <u>https://echa.europa.eu/contact</u>

 ¹⁵ Send the details - event name, dates, location, organisers, URL link, key speakers and/or other relevant additional information - to <u>reach-2018@echa.europa.eu</u>
 ¹⁶ ECHA's accredited stakeholder organisations (ASO):

organisations

¹⁷ World Trade Organization: <u>https://www.wto.org/</u>

¹⁸ Only Representatives Organisation – Best Practice Guide:

http://www.onlyrepresentative.org/images/download/oro/ORO%20Best%20Practice%20Guide%20v1_0 %2014%20May%202014%20final.pdf

5.6 Brexit - informal discussion

An informal discussion took place about the intended withdrawal of the United Kingdom from the EU. All NHDs shared a cautious stance that no regulatory advice on the possible outcome of the withdrawal can be given at this juncture.

5.7 Directors' Contact Group (DCG)

The Chair provided an update on the first two Sherpa meetings and the re-launch of the Directors' Contact Group (DCG)¹⁹. The informal platform was set up in 2010 in the run-up for the first registration deadline of phase-in substances. It was active then activated before the 2008 and 2010 registration deadlines and aimed to identify and resolve the priority issues of concern in meeting industry's registration obligations by providing an exchange of views between the European Commission, ECHA and industry associations. The Executive Director of ECHA chairs the group.

The Chair informed participants on the agenda items discussed in the Sherpa meetings of 17 January and 13 March 2017:

- **Portfolio rationalisation** and the fear that supply chains might be affected by companies not registering some important substances and potential impacts on the supply chain of the high and low volumes
- SIEFs beyond 2018, SIEFs without a lead Registrant
- Market intelligence on **registration intentions**
- The launch of an SME-focused **market segmentation** study that will allow ECHA to better target companies in various sectors
- Formal revocation of two DCG advisory documents, on the ECHA website:
 - 'Fair, transparent and non-discriminatory cost sharing in SIEFs', with a highlighted introductory statement that the Commission Implementing Regulation had become out-dated;
 - 'Recommendations on sound SIEF management', but without a similar reference to the Implementing Regulation. However, this document is still valuable and its recommendations are still valid. It might need revision and re-writing with more distinct and clearer wording.
- Access to financial support grant schemes in EU, as for example the European investment fund, and SME support programmes.

On the latter subject, the Chair also mentioned the importance of national initiatives to provide companies having to bear REACH-related costs with information on accessing **public and private finance**. He invited NHDs to bring forward such financial support schemes available in Member States so that DCG would gain a better overview of these schemes at EU level.

Also, on **national measures on promoting substitution** that can bring substantial benefits for companies, the environment and the health of workers and consumers (see list of action points, Annex III).

For the REACH registration deadline 2013, the DCG had upheld a limited number of **so-called 'DCG solutions'** to problems that registrants could face, without fault of their own, in the final stages of the registration process. The DCG would need to get back to these issues in early 2018 and communicate on their continued relevance in the immediate run-up to the 2018 REACH registration deadline.

¹⁹ Directors' Contact Group (DCG):

https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group

5.8 Questions & answers session

HelpNet members underlined the importance of substitution as the main objective of the European chemicals legislation, ensuring protection of human health and the environment. It was noted, that during the registration process, companies might become more aware of what they are producing, using and placing on the market and, in some cases, they may decide on the substitution of harmful chemicals with safer alternatives.

In some countries the authorities already have engagement programmes to support substitution, in some others, resources dedicated to substitution activities may be limited. In this regard, a HelpNet member suggested an awareness project on substitution endorsed by ECHA and the Commission; this could encourage industry to take actions to identify, develop and adopt safer alternatives to hazardous chemicals with the existing supporting tools.

The Chair mentioned the actions undertaken by ECHA²⁰ regarding substitution, interviews with companies and discussions on effective use of resources and sustainable use of safe chemicals. A report commissioned by ECHA is available for further reading²¹.

6. Updates from the European Commission and ECHA

6.1 Updates on BPR, CLP and REACH implementation

6.1.2 Updates from the European Commission on REACH and CLP

Temenuzhka POPOVA (DG GROW) presented an update on the REACH Regulation, specifically on substances of very high concern, authorisation, restrictions, nanomaterials, REFIT and other initiatives undertaken by the European Commission.

She informed on the feedback received from industry on the Implementing Regulation on data sharing²² after one year since the entering into force. Despite the general positive feedback, two main concerns have been brought forward, specifically the lacking of definition on what a 'potential registrant' is and joint work undertaken by the Commission and ECHA on clarifying what the 'every effort' concept means.

She further informed on the identification of three substances of very high concern²³ (SVHC) according to Article 57(f) of the REACH and the Commission's decision to review if the scope of Article 60(3) should be extended to substances identified under Article 57(f) as having endocrine disrupting properties with an equivalent level of concern to other substances listed as SVHC and the subsequent report²⁴.

Commission contributed to the guidance document 'How to apply for authorisation' and is currently working on the simplification of the **authorisation under REACH**, on a number of

http://eur-lex.europa.eu/legal-content/EN/TXT/?gid=1483624033123&uri=CELEX:52016DC0814

²⁰ ECHA's web pages on substitution, including case studies and webinars:

https://echa.europa.eu/regulations/substituting-hazardous-chemicals

²¹ Link to the report commissioned by ECHA on 'Needs and opportunities to enhance substitution efforts within the context of REACH':

https://echa.europa.eu/documents/10162/13630/substitution capacity lcsp en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b

²² Implementing Regulation on data-sharing:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN

²³ SVHC: bis(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate(DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

²⁴ Report in accordance with Article 138(7) of REACH to review if the scope of Article 60(3) should be extended to substances identified under Article 57(f) as having endocrine disrupting properties with an equivalent level of concern to other substances listed as SVHC:

Implementing Acts (i.e. for uses in low quantities, applications for authorisation for uses in legacy spare parts), and the Annex XIV amendment.

On **restrictions**, the Commission have already published the Annex XVII amendments as regards bisphenol A, and bis(pentabromophenyl)ether and working on the amending drafts for N-methyl-2-pyrrolidone (NMP), perfluorooctanoic acid (PFOA), phthalates, lead in PVC, tattoo inks, formaldehyde, etc.

Regarding **nanomaterials**, the impact assessment resubmitted by the Commission to the Regulatory Scrutiny Board was positively welcomed. The possible amendments of the REACH Annexes were discussed with the CASG-Nano; and the EU Observatory for Nanomaterials is under development.

Another important topic was the **Circular Economy** strategy and the publication of a Roadmap²⁵ on chemicals, products; the REFIT evaluation, and a joint work of DG GROW, ENV and EMPL on the interface REACH/OSH. The outcome will be part of the REFIT evaluation and will be presented in a workshop this year.

Finally, Temenuzhka POPOVA briefly noted the various **studies** conducted by the Commission, as for example:

- Finalised studies: study on low tonnages (1 to 10 tpa) polymers, enforcement indicators for REACH and CLP, study on Substance Identity (SID) in REACH, etc.
- Ongoing studies: study on costs and benefits of REACH authorisation

Maurits-Jan PRINZ (DG GROW) presented the Commission's update on the CLP Regulation, touching upon the June 2017 CLP deadline, the latest ATPs to CLP, poison centres, United Nations' Globally Harmonised System (GHS), important themes discussed in CARACAL meetings, and fitness check on chemicals legislation.

For retailers of mixtures the **deadline of June 2017** is approaching. Before 1 June 2015, any supplier (manufacturer, importer, downstream user or distributor) was entitled to attach a DPD²⁶ label on its mixture before placing it on the market, as long as it had been classified according to the same directive. The DPD labelling allows mixtures to remain on the market if relabelled after 1 June 2017. After that date, suppliers must attach a CLP label to the mixtures placed on the market.

ECHA will address this issue under the agenda item 7.2.4 CLP awareness campaigns, and Maurits Jan PRINZ encouraged NHDs to proactively engage in the discussions, especially targeted to distributors and retailers, affected by the 1 June 2017 deadline.

The three **ATPs to CLP** – alignments with the 5th, 6th and 7th revisions of GHS, timelines and transitional periods; harmonised classification that end up in the CLP Annex VI entries and which are based on the 2014, 2015 and 2016 RAC opinions; and other ATPs, as the harmonisation of information submitted to poison centres (Annex VIII) and translation of chemical names (Annex VI).

Due to the comprehensive presentation of ECHA at the CLP workshop, Maurits Jan PRINZ briefly touched upon the **poison centres** theme and the harmonisation information submitted to poison centres, starting with 2020 onwards²⁷. A lot of work will be done in the coming years by ECHA²⁸, industry, national authorities, and the Commission²⁹.

²⁵ Circular Economy Roadmap:

http://ec.europa.eu/smart-regulation/roadmaps/docs/plan 2016 116 cpw en.pdf

²⁶ Dangerous Preparations Directive (1999/45/EC)

 ²⁷ Deadlines: 2020 for consumer products; 2021 for professional products; 2024 for industrial products
 ²⁸ Working groups established on IT tools, guidance and one-stop notification portal

²⁹ Workability study launched on petroleum and construction products; discussion on-going on the definition of mixtures for industrial use

On **GHS**, there are two latest revisions³⁰, which will be bundled in one ATP to be prepared later in 2017, and possibly adopted early next year. Work is continuing also on: non-animal test methods used for classification purposes, precautionary statements, global list, explosives and additivity.

The following topics were on the agenda of the March **CARACAL meeting**:

- Soluble packaging and study with incident numbers to be presented at CARACAL-23
- Bioelution (CLP Article 12(b)) and the expert group led by ECHA
- Labelling of writing materials discussed at the HelpNet CLP Workshop last year
- (discussion expected at CARACAL-24, in June 2017)
- Labelling exemption for metals
- Bridging principles, long ongoing discussion and working group to be established.

Fitness Check on the most relevant chemicals legislation (other than REACH), aiming to assess whether the current legislative framework for chemicals is fit for purpose and delivers as expected. Multiple supporting studies were issued - first study (GROW) published, second study (ENV) on-going and a public consultation and SME panel was completed in 2016. These studies and other ones will feed in a final staff working document - fitness check report³¹ – that will be published by April 2018.

Maurits-Jan PRINZ highlighted some results of the public consultation, with a good score obtained by NHDs on effective support given to companies. However, there is still room for awareness raising as one third of the respondents indicated that they do not have experience with helpdesks.

6.1.2 Updates from ECHA on BPR and REACH

Theodora BASMATZI (ECHA) provided an update on REACH and BPR with focus on current issues on registration towards the last registration 2018 deadline and BPR developments.

Regarding REACH Regulation, she touched upon the implementation of JS in REACH-IT, manual completeness check approach and reasoning, lead registrant and data sharing – breaching cases. Complementing the presentation on actions undertaken by ECHA on existing registration dossiers (agenda item 3.5) Theodora BASMATZI addressed:

- Actions taken by ECHA against registrants breaching JS, ensuring that the OSOR principle is applied
- Reasons for introducing manual checks on submitted registration dossiers following experience gained by ECHA and (irrelevant) deviations from the standard information requirements
- *Ex post* TCC on registrations submitted after the implementation of the JS feature in REACH-IT and before the enhanced TCC
- Lead registrations without members and 'placeholder' dossiers submitted to occupy the JS lead position
- But also positive results showing that majority of registrants amend their dossiers and bring them with the standard information requirements.

She then informed on the impact of the Commission's Implementing Regulation on data sharing and JS and the increased number of disputes received by ECHA in 2016.

³⁰ Latest revisions: 6th revision (2015): new hazard class for desensitised explosives, new category for pyrophoric gases, miscellaneous changes and 7th revision (2017): new sub-categorisation for flammable gases, guidance on precautionary statements, example of fold-out label, minor technical changes ³¹ Fitness check on chemicals legislation (excluding REACH):

http://ec.europa.eu/growth/sectors/chemicals/ec-support_en

Regarding BPR, information was provided on:

- Data sharing, disputes and appeal cases so far
- Legislative developments: Review Programme, non-approval of certain biocidal active substances, authorisation of same biocidal products, and endocrine disrupting properties
- Important BPR deadlines linked to Article 93 and Article 94 provisions.

6.2 Updates of on-going ECHA activities

6.2.1 Guidance activities

Peter MEGAW (ECHA) presented a summary of the guidance activities initiated and/or completed since the last presentation to the HelpNet in April 2016.

Update on publications already reported as under consultation in April 2016;

- REACH Guidance on IR & CSA, covering e.g. occupational exposure assessment, framework for exposure assessment, consumer exposure estimation
- CLP Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008
- BPR transitional Guidance on: efficacy assessment for Disinfectants (Product Types 1-5); Guidance on active micro-organisms and Biocidal Products; transitional Guidance on efficacy assessment for Product Type 14 Rodenticides

Updates to the key documents needed by registrants for the 2018 REACH deadline have already been published (e.g. updated Guidance on Registration, Guidance on data sharing).Drafts are already available on the ECHA website for all REACH-2018 relevant guidance and the final versions can be expected before summer 2017.

Other updates on guidance already foreseen in April 2016:

- Further update to the Guidance on requirements for substances in articles
- Guidance on IR & CSA
- Update 'Guidance on Identification and naming of substances under REACH and CLP' to implement the provisions of the new Implementing Regulation on JS of data.

Work continues on BPR & CLP guidance and Guidance on nano-materials³², the latter foreseen for May 2017:

- Guidance on Nano forms (New Appendix to the guidance on registration)
- Guidance on Information Requirements (IR) for nanomaterials for Human Health
- Guidance on IR for nanomaterials for the environment
- Guidance on Read-Across for Nano forms

Work has been initiated on guidance concerning endocrine disruptors and on guidance for 'poisons centres' (harmonised information relating to emergency health response – new annex to CLP referred to in Article 45 of CLP).

6.2.2 Forum activities

Maciej BARANSKI (ECHA) provided an update on Forum activities, specifically on current and future Forum projects, formation of the Forum BPR subgroup and other activities (e.g. trainings) of interest to the HelpNet.

³² See: <u>http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach</u>

Forum projects:

- REF-4: Restriction entries, currently collecting results from national coordinators. Report expected in 2017/Q4
- REF-5: Extended safety data sheets, exposure scenarios, implementation on risk management measures and operational conditions. Report expected in 2018/Q4
- REF-6: Classification and labelling of mixtures with check of SDS. Report expected in 2019.

Pilot projects:

- Authorisation 2 substances subject to authorisation on the market and check of the compliance in the supply chain and conditions in granted authorisations. Final report expected in mid-2017.
- CLP child resistant fastenings (article 35(2) of CLP, except Liquid Laundry Detergent Cups (LLDC)). Report published in June 2016.
- CMRs and skin sensitisers ECHA has provided cases of non-compliance where registrants failed to apply harmonised C&L for CMR and skin sensitising substances. Report published in June 2016.
- Internet sales of mixtures (CLP), check compliance according to Article 48(2) of CLP. Report will be published in 2018.
- Substances in articles, with focus on checking duties under Article 7(2) and 33(1) of REACH. Report will be published late 2018.
- Interlinks, follow-up of ECHA decisions by NEAs and cooperation with ECHA. Guide on interlinks finalised in June 2016.

Future pilot project: PIC, notification of exports

Future pilot project or REF-7: Intermediates.

In 2016, the Commission established a **Biocides Enforcement Group** (BEG) to cooperate on BPR Enforcement. BEG met three times, back to back with Forum plenaries. In February 2017, Commission (DG SANTE) requested ECHA (in line with Art 76(1)(h) and Art 76(1)(l)) to provide support and assistance to Member States (MSs) with regard to enforcement activities related to BPR.

ECHA established a formal **Forum BPR Subgroup** (BPRS), which will meet for the first time on 31 March 2017, in Helsinki. BPRS will be tasked with coordinating the network of national MSs' authorities responsible for the enforcement of BPR Regulation. BPRS will discuss about enforcement priorities, Work Programme 2017-2018, cooperation with REACH and CLP Forum members and enforcement projects.

Lastly, he informed participants that the Forum Training for Trainers in October 2016, on **'Extended SDS and exposure scenarios'**, was attended by 16 HelpNet REACH members, 53 Forum trainees, one participant from the Commission and 58 remote participants. The event was very successful: 100% of participants physically present (and 94.1% of remote participants) rated it as either 'good' or 'excellent'.

The Training for Trainers of this year will be dedicated to '**Classification and labelling of mixtures and Authorisation**' and will take place from 4 to 5 October. HelpNet REACH or CLP correspondents were invited to participate in the training. The details will follow from the HelpNet Secretariat.

The Chair invited the CLP members to indicate by answering to a short SliDo poll, if in the absence of funding from ECHA, CLP members would be interested to attend the training on the expenses of their national authorities.

6.2.3 Communication activities

Jakob AAHAUGE (ECHA) presented ECHA's envisaged new microsite for the general public. The site will have a distinct structure and new design and will contain information tailor made for the general public. The aim is to allow for better targeted communication with a specific audience, within a space made only for them, with an easily understandable content and simple language.

Based on the results of the consumer survey, with feedback received from more than 1,000 respondents, ECHA is working now on the content, planning to launch the site in November this year. Participants to the survey have proposed the following topics for the microsite: chemicals in our home & how chemicals improve our lives, chemicals in consumer products, chemicals and health/environment, safety for workers and benefits of REACH.

Tiiu BRAUTIGAM (ECHA) informed on the latest awareness activities undertaken by the REACH 2018 Communicators' network in reaching out companies affected by the last REACH registration deadline that are first-time registrants, many of them SMEs.

The network was established in 2015 and includes members from the Member State competent authorities, national helpdesks, industry organisations, Enterprise Europe Network and ECHA. It works on a voluntary basis, and mainly virtually.

Its task is to coordinate awareness raising activities for the last deadline of 31 May 2018, coordinate communication activities across the EU Member States and organisations to maximise outreach, to develop and share communication products, and to harmonise messaging through various means of channels, e.g. media, social media, events.

This year, the members of the REACH 2018 Communicators' Network will hold a WebEx meeting in May. The second meeting will be in October in Brussels, with the stakeholders' communicators.

To maximise the impact of communication on chemicals safety around Europe, ECHA would like to combine these two networks into one and include more communicators from the competent authorities. The goal is to reach out to consumes and workers in Europe.

Tiiu BRAUTIGAM invited MSs not represented in the network to join³³ and all NHDs to raise awareness of industry from their side.

7. REACH and CLP campaigns

7.1 REACH - toolkit for promoting the REACH 2018 registration

Hanna-Kaisa TORKKELI (ECHA) showed the participants the new animation for the first phase of the REACH 2018 Roadmap to successful registration and highlighted the REACH 2018 Toolkit web page. She encouraged national helpdesks to make use of the support packages that the toolkit provides and also to propagate the toolkit towards industry and sectoral associations within their countries. The web page includes ideas and material to promote the last registration deadline.

The toolkit can be accessed at: <u>https://echa.europa.eu/reach-2018/toolkit-for-promoting-the-registration-deadline</u>

³³ If you are interested, contact ECHA by email: <u>reach-2018@echa.europa.eu</u> or fill in the contact form available on ECHA website, at: https://comments.echa.europa.eu/comments cms/MSCA ITsupport form.aspx

7.2 Market place

The interactive part of the meeting was held in a new format. The selected five topics were presented in five different stands. The participants were invited to split equally at the beginning of the session. After a brief presentation of each topic, the floor was open for discussion. The participants were free to move from one stand to the other following their own interest, at any time. In this way, they could focus on those topics in which they are most interested or for which they can provide more elaborated input.

7.2.1 VLARIP & WALRIP 10 years of joining forces to implement REACH

Moderator: Tine CATOOR

ECHA: Katarina CENDIC and Pedro ROSELLÓ VILARROIG

The discussion went over several topics, from conceptual issues to more practical ones. A recurring topic was the motivation of the mentors in helping other companies which, at a first glance, are potential competitors.

Tine CATOOR explained that mentors had very soon identified several benefits, the first one being getting to know the uses of the substances they manufacture and import along the supply chain, when it come to their customers. When the mentees were not their customers, helping them avoided them becoming free riders.

From an organisational point of view, all participants benefit from a dedicated support from Essenscia, which is always something to be valued. However, these groups and workshops cannot be extended to maximize the use of resources: the limit is the activity of the members. In other words: if the group is too large, the members start to become passive and the benefits dilute.

The programme is not for free in Flanders, although a 50% reimbursement can be expected. This cost is not a deterrent for SMEs who see they get value for their money, namely a support group available for a long time, beyond classic training sessions, and also constant hands-on training. The approach taken by these groups is working on practical experience and doing the work.

An important aspect in the success of the mentoring programme has been the involvement of the competent authorities (CA) and national helpdesk (NHD). This involvement has ranged from promoting the programme³⁴, providing speakers to the workshops to setting up a reimbursement plan (50% in Flanders, free in Wallonia).

Finally, the mentoring programme is indeed focused on REACH and CLP, but the members can request other topics within and beyond these Regulations. Some of the topics that have been discussed already are the Authorisation process and looking into the overlaps and connections with other pieces of legislation.

Summary of discussions is provided in Annex II.

7.2.2 REACH 2018 SME workshop in Vienna & REACH 2018 and beyond

Moderators: Peter SCHINDLER (Austria) and Temenuzhka POPOVA (DG GROW)

ECHA: Olena KRYCHEVSKA and Martin ALBERT

Summary of discussions is provided in Annex II.

³⁴ See the promotion video:

https://www.youtube.com/watch?v=66WTCsKO_xw&feature=youtu.be

7.2.3 Tour de France seminars & REACH seminar in Cyprus

Moderators: Nathalie HAYAUD (France) and Maria ORPHANOU (Cyprus)

ECHA: Christina LOUKOU and Guiomar SAUCEDO-CUEVAS

Nathalie HAYAUD (FR) and Maria ORPHANOU (CY) presented the 'Tour de France' seminars and the REACH seminar in Cyprus, respectively, as part of their SME-targeted activities related to the REACH 2018 Registration deadline.

1) 'Tour de France' seminars (FR)

Nathalie explained that these seminars were implemented through a national action plan for SMEs led by the Ministry of Environment, in partnership with the French helpdesk, the French Chamber of Commerce and EEN representatives. They plan to deliver 24 seminars all around France in 2017, where more than 1000 companies (mainly SMEs) are expected to attend. Natalie also highlighted that, so far, the interested public has mainly been downstream users.

2) 'How does the REACH 2018 Registration affect your business?' seminar (CY)

Maria ORPHANOU explained that the Cypriot helpdesk prepared this seminar in collaboration with ECHA, the enforcement authorities (LIFE CHEREE program) and the EEN representatives. This seminar was targeted at companies with registration obligations. However, other seminars targeting different groups have taken place or are planned. Approximately 100 companies (mostly SMEs) participated in the event, and the interested public was mainly importers.

Observations that came up during the session:

During the seminars in France and Cyprus, the one-to-one sessions were greatly appreciated (e.g. parallel sessions with ECHA & enforcement, CY). In addition, large breaks promoted networking and exchange of experiences between participants. Common questions asked by the registrants were related to REACH 'certificate', scope of registration/exemptions, data/cost sharing and SIEF issues.

The participants of the market place session pointed out that there is little awareness amongst SMEs on their REACH obligations, and that registration is deemed costly and bureaucratic. It was noted that the presence of enforcement authorities at customs level can help increase awareness of importers. The national action plan for SMEs (FR) was considered helpful for the practical organisation of related events. Nevertheless, the difficulty in targeting specific roles/ sectors (mixed audience) by similar events was highlighted. Summary of discussions is provided in Annex II.

7.2.4 CLP related awareness-raising activities

Moderators: Adam ELWAN and Outi TUNNELA (ECHA)

Adam ELWAN introduced the participants to the item by naming two groups to whom campaigns will soon be targeted: 1) **consumers** and 2) **retailers**.

1) **The video** 'Know the labels' will be published on ECHA's website on 9 May 2017 (Europe Day). The aim is to raise consumer awareness of the new CLP pictograms. The video was presented in advance during this session.

2) **The deadline** 1 June 2017³⁵ for retailers is approaching. ECHA will send **information** to NHDs in early April regarding **retailers**, to remind about the forthcoming deadline. There are several channels to provide information like website, Twitter, Facebook and LinkedIn. The use of social media might be an effective way to disseminate information and get messages out.

The main findings of **the interactive info session** on the CLP-related awareness-raising activities and the action points are provided in Annex II.

7.2.5 Feedback from participants on the REACH toolkit

Moderator: Hanna-Kaisa TORKKELI, Laura WALIN and Anisa KASARUHO (ECHA)

The Toolkit for promoting the REACH 2018 registration deadline was introduced to the participants. It was explained that it is a collection of ideas and actions that help raising awareness among SMEs, about the deadline. The ideas were illustrated and discussed with the participants.

In general, the participants found the toolkit useful and inspiring. They hightlighted that novel products could be used to target SMEs, such as, audiofiles, videos for importers, as well as TV and radio spots.

It was concluded that it is helpful if ECHA provides NHDs with tips about targeted usage of social media, as well as text to be used for awareness raising articles, in the national generic media. In turn, NHDs could contact the national media. Also, NHDs should consider translating the REACH 2018 Roadmap webinars. It was pointed out that English scripts of the webinars are available in S-CIRCABC. Finally, everyone was invited to make best use of the REACH 2018 Toolkit in their respective countries.

Main key oucomes and action points are provided in Annex II.

Closing of the HelpNet Steering Group meeting

The Chair closed the meeting concluding that HelpNet 12 events covered most current and relevant topics on REACH (with a view to the 2018 registration deadline and changes in ECHA's regulatory processes), CLP (state of play concerning nanomaterials and the CLP Regulation, poison centres) 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 in 2017: REACH workshop possibly in July and September and CLP workshop possibly in November. Discussion will continue on the participation of NHDs to the October Forum training on authorisation and Chemical Safety Assessment.

The Chair thanked all correspondents and observers for their active and valuable contribution to the 12th HelpNet Steering Group meeting and the 10 year anniversary of the network.

³⁵ Ref. Article 61 of the CLP Regulation on transitional provisions: 'mixtures classified, labelled and packaged in accordance with Directive 1999/45/EC and already placed on the market before 1 June 2015 are not required to be relabelled and repackaged in accordance with this Regulation until 1 June 2017'

8. BPR Workshop

The Chair welcomed the BPR correspondents and observers to the BPR Workshop and the Commission's representatives attending by videoconference.

8.1 Update from the Commission on the BPR implementation

Martinus NAGTZAAM, Pilar CASADO DE AMEZUA, and **Alfonso LAS HERAS** (DG SANTE) presented the Commission's update on the BPR implementation and enforcement, specifically on the following areas: HelpEx, union authorisation, rodenticides, enforcement, Article 65 reporting, maximum residue limits (MRLs), and endocrine disruptors (ED).

Martinus NAGTZAAM informed that the CA meeting endorsed the revised process for the BPR questions in **HelpEx**.

Regarding **union authorisation** (UA), he mentioned that a major priority of the year is to set up the authorisation system and ensure consistency between UA and national authorisation while meeting the legal deadlines³⁶.

Alfonso LAS HERAS highlighted the major objective reached in June 2016 together with CAs, ECHA colleagues and BPC members in optimising the renewal process of anticoagulant **rodenticides**:

- The work done in the Coordination Group (CG) and harmonised SPCs
- Early implementation of the agreed risk management measures (RMMs)
- Optimisation of the renewal process & the implementation of the 9th ATP

He also mentioned other important steps, as the ongoing work on the Review Programme Regulation and the:

- Decisions on renewal of all Active Substances (ASs) by December 2016
- Submission of additional data for PA renewal by February 2017 and ongoing applications for renewal due to technical issues on which the Commission and ECHA have taken actions
- RefMS AR and draft SPC by August 2017.

The Commission handed over the **BPR enforcement** to ECHA and the coordination will happen under the umbrella of a subgroup of the Forum. The Biocides Enforcement Group will meet on 24 March 2017, during the Forum meeting, in Helsinki.

Pilar CASADO DE AMEZUA introduced the next topic, the **Article 65 of BPR³⁷**. The Commission will develop a template which will be used by Member States to report on the status of the implementation of BPR as of Article 65 in due time.

Commission informed about the setting **maximum residue limits** (MRLs) for food and feed with respect to active substances contained in a biocidal product and about specific migration limits for residues in food contact materials. The established interim policy approach should provide the balance with two objectives: limiting consumer exposure to residues and ensuring microbiological safety.

MRLs should be established when measurable residue levels can be found in food as a result of the use of the biocidal product for which authorisation is requested, and when the applicant fails to demonstrate that the residue levels do not pose a risk.

³⁶ Deadlines for Union authorisation applications: <u>https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation/deadlines-union-authorisation-applications/2016</u>

³⁷ CIRCABC: <u>https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b</u>

Commission highlighted a connection to other legislation, such as food contact materials (FCM), veterinary medicinal products (VMP), plant protection products (PPP) and contaminants. For example, default MRLs defined under PPP legislation apply to a biocidal active substance used as PPP formerly. There will be a need for analytical methods for relevant residues to establish levels of residues where necessary.

The interim approach is implemented in relation to other legal frameworks and will be updated in three years.

Update on the progress on EDs. On 15 June 2016, the Commission adopted a Communication of the Commission to the European Parliament and the Council on EDs and presented the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products (PPP) and biocidal products.

This communication places the established scientific criteria for BPs in a broader context, in particular the link with the setting of scientific criteria for the determination of endocrinedisrupting properties in the domain of PPP, the implication for other regulatory areas and other on-going activities of the Commission on ED.

The criteria put forward by the Commission contain three elements:

- The definitions on ED and adverse effects set by the World Health Organisation (WHO) in 2002 - through its International Programme for Chemical Safety – in 2002 and 2009. Those definitions have by now reached the widest consensus among scientists
- The endorsement of these definitions by the European Food Safety Authority (EFSA) in its scientific opinion on EDs adopted on 28 February 2013
- And the view of the Scientific Committee on Consumer Safety

It is therefore considered appropriate to base the criteria for the determination of ED properties on those WHO definitions.

The criteria for the determination of endocrine disrupting properties reflect the current state of scientific and technical knowledge and discussions in a group of MS experts and the Standing Committee (PRAC measure) for PPPs. After the scrutiny and adoption steps, a transitional period of 6 months will follow before the ED criteria will be applicable in all MSs.

8.2 Questions and answers session

The Q&A session started with a question based on the information provided on ECHA's website on the SME verification process³⁸:

Question:

How will be stakeholders involved in the development of the Article 65(3) report template?

Answer:

The Commission is working on a draft template which will be used by MSs to report data under Article 65(3) of BPR. The Commission is currently collecting feedbacks among the CAs and the BPR Forum Subgroup members in order to better cover the needs of the MSs. The plan is to present the state-of-play of the project at the next CA meeting in May 17 and at the next BPR Forum Subgroup meeting in June 17. Once a final template will be endorsed, the Commission will share it also with the National Helpdesks.

³⁸ 'How to determine the company size category' available on ECHA's website, at: <u>https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-fees-under-bpr</u>.

Question:

How much time before the submission deadline is needed for a company to provide the supporting documentation in R4BP, for the SME status recognition?

Answer:

Within 45 days of receipt of all the relevant documents, ECHA will decide if the SME status can be recognised. A recognition of an enterprise as an SME will be valid for applications submitted under BPR for two years.

On the presentation given by the Commission, one NHD noted the lack of harmonised views on borderline cases, specifically medicines and medical equipment.

The Commission agreed that disinfectants are looked at in different ways in different MSs.

Another NHD stressed that BPR scope issues shall be dealt with by MSs only. The Commission's representative reminded the suggestion made in the last CAs meeting that a short discussion document with information that took place in HelpEx shall be submitted to the biocides CA meeting. If a conclusion is reached during the meeting this would be recorded in the minutes and NHDs could make a reference to the document available on CIRCABC, in the future.

8.3 Active substance approval - update from the Biocides Assessment unit

On behalf of the Biocides Assessment Unit, Valerio SPINPOSI (ECHA) gave an update on the relevant time limits for PTs in the Review Programme, the Commission Review Programme Regulation amendments³⁹ and BPC work programme⁴⁰ 2014-2017.

He presented some statistics on the number of applications and notifications received in the last one-year and a half, as for example: in situ generated active substance and treated articles, free radicals, applications under Article 93 and the consequences of Article 93 and 94 of the BPR on active substances currently on the market. He underlined that the work to be performed by MSs at national level is linked with the inclusion of new active substances in the biocides framework. Thus, it remains very important to harmonise the support provided to industries from ECHA and NHDs.

He provided information on comparative assessment for anticoagulant rodenticides, and the situation on request on food and feed derogations. Clarifications was also provided on the different deadlines established by the Review Programme Regulation that ECHA managed in the course of 2016. NHDs raised some questions about the current situation of ozone generated in situ and specific deadlines to respect in order to keep the products on the market.

Question:

Is the final list of Article 94 substances with reference to treated article already available on the ECHA website?

³⁹ The 1st amendment: not supported Annex II part B and nano-forms:

 <u>CA-Sept16-Doc.3.2- Amendment Review Regulation draft Act.docx</u>

 <u>CA-Sept16-Doc.3.2- Amendment Review Regulation_draft Annex.docx</u>

The 2nd amendment, probably in 2018, in-situ, withdrawals and food & feed (not belonging to Annex I) ⁴⁰ BPC work programme on ECHA website, at:

https://echa.europa.eu/documents/10162/17287015/wp active substance approvals 2016 17 en.pdf/f e3698a4-c6c5-4e41-bbfc-06ba64f283db

Answer:

Soon, ECHA will publish such list on the dedicated section of the ECHA website for treated articles. The list will presumably show the substance/product-type combinations submitted by 1 September 2016.

- In a first part it will contain substance/product-type combinations which are under examination or have been approved. Articles treated with a biocidal product or intentionally incorporating a biocidal product containing these active substances are legally on the EU market.
- The second part of the list will contain substance/product-type combinations for which a submission was made by 1 September 2016, but the submission was rejected or a non-approval decision was adopted. Articles that were treated or incorporated a biocidal product containing those active substances should no longer be placed on the market as from 180 days from that rejection or non-approval decision.
- Finally, the third part of the list will show substance/product-type combinations notified for inclusion in the Review Programme for which ECHA has issued a declaration of compliance in accordance with Article 17(5) of the Review Programme Regulation (or where such a notification is being processed). The list includes notifications made for redefined active substances, substance/ product-type combinations in part two of Annex II to the Review Programme Regulation substances that previously benefitted from the food & feed derogation, substances where the product-type was modified under the BPR compared to the BPD. The active substance approval application is expected to be submitted by the participants within 2 years of the relevant notification compliance decision. Articles treated with a biocidal product or intentionally incorporating a biocidal product containing these active substances are legally on the EU market.

Question:

Within the scope of Article 93 of the BPR, what are the differences in term of transitional measures between ozone generated from natural sources/ozone generated from oxygen and active substances generated in situ currently included in the Review Programme Regulation?

Answer:

Where an application for approval of the in situ active substance/product type combination was submitted by 1 September 2016 (under Article 93 of the BPR), the precursor system will benefit from the extended deadlines to be made available on the market and used set out in Article 89(2),(3) and (4) of the BPR. Where an application was not made by 1 September 2016, the derogation lasts only until 1 September 2017.

The Article 93 transitional measures only apply to biocidal products consisting of, containing or generating only active substances that were available on the market, or used in biocidal products, on 1 September 2013 and that were not supported under the Review Programme or were supported for different product-types than the ones for which they are used.

Indeed, the in situ active substance/product type combinations submitted by 1 September 2016 (within the scope of Article 93) will not be eventually included in the Review Programme Regulation.

As soon as the European Commission will verify the draft list prepared by ECHA with reference to Article 93 applications, it will be made publicly available on the ECHA website accordingly.

8.4 Update on IT

Valerio SPINPOSI (ECHA) presented the **recently added features** in R4BP3 and SPC Editor in the view of the new feature of the Review Programme Regulation.

Among other functionalities, a focus was given on the new structure for Product Family and the same biocidal product authorisation, the management of the UA applications, an overview of new case types in R4BP3, and process flow improvements.

For practical information on BPR requirements, and detailed and illustrative technical assistance, NHDs were asked to guide their customers to the **Practical guides**⁴¹ and the **Biocides Submission Manuals**⁴² on ECHA's website. The Biocides Submission Manuals describe how to build IUCLID dossiers for the various Biocidal Product Regulation applications and how to submit and manage those applications in R4BP 3 until a successful outcome is achieved.

Concerning the R4BP, some NHDs stressed a few technical issues that could be improved, as it would make the IT tools more user friendly: many mouse clicks are currently needed to access certain information and it is not always possible to have all the listed items on one page. Also, an increased number of characters would be necessary. ECHA promised to consider the feedback⁴³ received on the IT tools and see how these wishes could be accommodated.

Valerio SPINPOSI (ECHA) highlighted also the **upcoming features in IT Tools**, in the following areas: new case types, grouping, process flow improvements and improved display and communication through the tool.

He encourage NHDs to look at constantly updated manuals on S-CIRCABC, particularly the R4BP 3.8 (3.10) **Manual for Authorities**⁴⁴ and the R4BP 3.10 **Manual for the European Commission**⁴⁵.

Question:

How will UA be processed in R4BP 3?

Answer:

According to the Regulation and with the IT implementation, the Comission shall grant the UA.

The authorisation will be published in the Official Journal (OJ). At the moment we still don't know if the SPC will published in the OJ as well or the OJ will make reference to ECHA's dissemination webpage. In case the first scenario will be implemented, there will be a need to publish an amendment in the OJ each time the SPC is modified in the asset.

 ⁴¹ Practical guides: <u>https://echa.europa.eu/practical-guides/bpr-practical-guides</u>
 ⁴² Biocides Submission Manuals:

https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

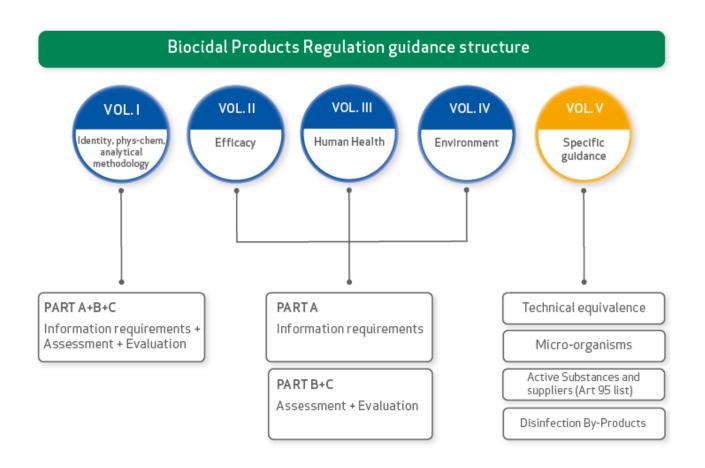
⁴³ NHDs can send their proposals for R4BP improvement to ECHA using the contact form available on ECHA website, at: <u>https://echa.europa.eu/contact</u>

⁴⁴ The CA Manual 3.9 will be available on S-CIRCABC, for the national authorities IT support users

⁴⁵ COM Manual will be available on line in November on S-CIRCABC

8.5 Update on Guidance documents

Stella JONES (ECHA) from the Support, Forum and HelpNet Secretariat Unit presented the new BPR guidance structure⁴⁶, outlining the gaps filled in the last year and the guidance activities planned for 2017.



NHDs welcomed the new structure of BPR Guidance and the simplifications made.

She highlighted that there were seven BPR Guidance documents published in the last year including:

- Three Transitional Guidance documents that were now incorporated into the recently published Volume II on Efficacy, Assessment and Evaluation,
- A new Volume V Specific Guidance on Disinfection By-Products
- Updates to the Volume V Specific Guidance on Micro-organisms and to Volume III on Human Health, Assessment and Evaluation.

She also gave a brief account of current projects including:

- Seven updates in total to the Assessment and Evaluation (Parts B+C) of Volume II, Volume III and Volume IV
- An update to start later in the year on the Volume V Specific Guidance on Technical Equivalence
- The development of Volume I to include Parts B+C on Assessment and Evaluation.

⁴⁶ Guidance on biocides legislation:

https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

8.6 HelpEx questions

Nicola TECCE (ECHA) gave a brief overview about the recently endorsed CA paper on the revised approach on HelpEx. He mentioned that the following paragraph has been included in the CA paper in order to address the so-called 'scope issues' on HelpEx:⁴⁷

'The ECHA Secretariat internally notifies the Commission for questions outside ECHA's remit, which may fall in the Commission's remit (e.g. scope issues). If needed, Commission will directly post on HelpEx the suggested follow-up actions, adding some reasoning (e.g. issue to be raised at the CA meeting for further discussion and agreement; issue to be handled by an Article 3.3 request; etc.). In case the issues can be independently handled by the HelpNet members, no further involvement from Commission is expected on HelpEx.

There is still some uneasiness on how to best capture the conclusions related to scope issues taken at the Biocides CA meetings. These questions are indeed in the remit of the MSs and ECHA is not going to publish them on ECHA website.

It was clarified that only Q&As in ECHA's remit will be published on the ECHA website as FAQs. It was suggested that MSs would always capture scope issues via a paper that would be discussed and concluded at the Biocides CA meetings. When a decision is taken through an Article 3.3 request, the ultimate legislative act issued by Commission is then published on the ECHA website⁴⁸.

It was also suggested that Commission could possibly save on CIRCABC, in a dedicated folder, papers containing the outcome of decisions related to scope issues that are discussed in HelpEx and then endorsed at CA meetings.

ECHA will take care of this action point and follow up the proposal with the Commission. If agreed ECHA will present a line-to-take at the next HelpNet meeting.

It was highlighted that the final goal is to create a knowledgebase in HelpEx covering both scope issues and questions in ECHA's remit. This knowledgebase is valuable in order to harmonise the support provided to companies around Europe.

Finally, the owners of scope issues in HelpEx have been asked to analyse all the pending scope issues currently in HelpEx and decide on the most appropriate action to take:

- Actively consult the Commission (or ask ECHA to do so)
- Bring the issue to a CA meeting via a paper
- Initiate an Article 3.3 request
- Close the pending scope issue if solved already (and post the outcome of the discussion).

It is very important that owners of scope questions in HelpEx will post the final replies in HelpEx once they become available.

 ⁴⁷ CA-March14-Doc.7.5 - HelpEx and e-consultations.doc: <u>https://circabc.europa.eu/sd/a/2aeda230-df63-4eb9-9acb-9d48bac0d680/CA-March14-Doc.7.5%20-%20HelpEx%20and%20e-consultations.doc</u>
 ⁴⁸ List of current Article 3.3 decision issued by Commission and availate on ECHA website at: <u>https://echa.europa.eu/regulations/biocidal-products-regulation/legislation</u>

8.7 Grants for SMEs – Danish experience

Vivi JOHANSEN from the Danish Environmental Protection Agency (DEPA) presented the support given through grant scheme to SMEs.

DEPA decided to fund a scheme for SMEs and announced the grants in September 2016. To be eligible for the grant, companies needed to use active biocidal substances that are considered less burdensome on human health and the environment. Enterprises, trade associations and consultancy companies participated to the information meeting launching the programme.

The grants were only given to applicants using these less harmful active substances. This meant that the company either wanted to put a new active substance on the list of substances that are known to be less harmful, or to get an authorisation for a biocidal product that was using these Annex I substances.

Four applications were received within the two-month deadline. After careful assessment, three companies were granted funding. One company received the grant to apply for product authorisation for an in-can preservative for their paints.

Two companies received funding to get willow extract and glycerine on the EU's list of less harmful active substances. If the substances are put on the list, they can be used as less harmful alternatives to the existing solutions to deter insects, for example.

The successful applicants were all companies whose main business were not biocides – but who had come across a good idea with biocidal potential as part of their business. Because their day-to-day work was focused elsewhere, they would not have had the time or the means to do the tests and put together an application. The feedback DEPA got was that, without the grant, they would never have even pursued these alternatives.

The results will be available in 2018 and 2019. From now until 2019, the companies will test their substances and products. DEPA hopes that the grants will be followed by applications.

Vivi JOHANSEN said that the scheme also helped raise awareness of the EU biocides obligations. DEPA knew that small companies were facing challenges with biocides. Companies might not even know that a biocides regulation exists or that they need an authorisation to sell their products. The Danish authority will continue to help companies with information and guidance on the rules for approving less harmful biocides.

DEPA hopes to repeat the scheme in the future. Based on their experience, they would definitely recommend a similar funding scheme for any EU country, if budget allows.

Closing of the BPR workshop

Conclusions by the Chair

The Chair gave a short wrap-up of the meeting, thanked all BPR participants for their active and valuable contribution to the workshop and informed that the action list will follow after the meeting.

Annex I - CLP Workshop – break-out group summaries

4.4.1 Break-out group - C&L according to form/state

A Linseed oil -based paint classified as STOT RE1, H372 - *Causes damage to lungs through prolonged or repeated exposure by inhalation* was presented as an example. The classification was based on the concentration of cristobalite (silicon dioxide). However, the paint as put on the market is thick/sluggish and does not dust. Dust is produced when the paint is sanded off the wall.

At the previous workshop it had been mentioned that such a paint should not be classified based on the given effects. At the present workshop this was echoed by some but now also opposed by others. It was interesting to see how the views were diverging.

Views **for not classifying** the paint (or similar) could be summarised as follows:

- The exposure and life cycle of a product should not be taken into account when classifying such a mixture
- Such later stages as e.g. scraping the paint off from the wall should not be taken into account as this is no longer a use of the mixture.
- The adverse effect seen from dust when scraping of the paint could be physical, similar to the effect caused by any dust and not chemical due to this particular substance/mixture.
- It is important to give the users proper label information and avoid over-labelling.

Views **for classifying** the paint (or similar) be summarised as follows:

- The intention of the rule is to take into account that, for example, a nanoform or a powder could have different (additional) hazardous properties than the solid bulk.
- The rule is based on a footnote in UN GHS chapter 1.1, which refers to physicochemical properties (pressure, temperature, flammability) and which to some extent are also dependent on external factors (e.g. dust only explodes when there is an ignition source).
- The paint on the wall has a function and thereby is still in use (perhaps not by the painter, but still in use) and could also in this stage be taken into account for the classification.
- Even if the paint is in a form that does not immediately reveal the hazard, the user (e.g. professional painter) should be informed about the possible adverse effects caused by the paint, so the user has the opportunity to choose also on these grounds.
- It is important to keep classification strictly hazard-based and not open to exposure and risk thinking. Exposure comes at a later stage and could perhaps be subject to any labelling derogation (similar to some that already exist), but should not be part of classification.
- It is important to pass on information about the intrinsic properties through e.g. an SDS to professional users to ensure that proper information will follow to any subsequent handling of the product. This can prevent unsupported uses (misuse), e.g., dilution and spraying..

Several participants seemed unsure of what the current guidance says and agreed that it could be a good idea to check it and possibly add some examples. The diverging views may make the task difficult, however, and there may be a need to first resolve some policy aspects of the topic at e.g. the CARACAL.

4.4.2 Break-out group - Use of REACH data for classification purposes

- 1) The registration dossier contains studies and data but they are owned by the registrants. How can you get permission to use the data? Can you trust it?
- Most agreed that the information from registrants, where publicly available, can be used
- Question raised: the registrant owns the study but does he own the result?
- Some felt it depends on who is asking for the data. E.g., if DU uses it classify a mixture, then perhaps yes, but if the data being used for another regulatory purpose e.g. BPR, then no?
- Question was raised: who is going to police who is using the data?
- CLP requires most 'up to date' information
- Discussion on what does 'available data' mean legally?
- Who owns data published on dissemination site?
- Discussion on the variations in the C&L inventory and would the 2018 registration improve that?
- Some wondered was this question premature?
- Agreed on need to revert to own supply chain to verify classification unless in the same supply chain as registrant to ensure it is adequate and reliable.
- Some felt FORUM (Ref 6) project on C&L of mixtures might improve collaboration between registrants and notifiers on different C&Ls
- Also discussed that validity of data depends on the source, i.e. imported substance in a mixture versus substance manufactured in the EU.

2) Data generated under REACH should be enough to derive a classification. But that data is not always generated with classification criteria in mind? So you can use REACH data - but sometimes (often?) it can only be used as WoE.

- Yes, it can be used but, in practice, it is challenging and problematic
- REACH advocates the use of alternative test methods (QSAR, in vitro, grouping, readacross)
- These do not have CLP classification criteria available so WoE is required
- Example is new skin sensitisation information (Annex VII, point 8.3)
- Majority felt WoE not used in practice in supply chain
- SMEs /formulators very far removed , helpdesks not being asked such questions and appears to be a concern at RAC
- Downstream users rely on SDS software packages to derive the classification of mixtures
- Some tests requested under REACH may not be best suited to derive a classification under CLP without the use of WoE.

3) Does the guidance on REACH contradict the guidance on CLP? There seem to be such situations (examples?)

- Only example provided was for sensitisation where the guidance on REACH and CLP differ;
- Most NHDs felt this question was very far removed from their experiences with SMEs and formulators
- More of a concern at the top of the supply chain with M/I who have the responsibility for the classification of substances.

- 4) Can existing adequate test data which have been generated by test methods not mentioned in Regulation 440/2008, as amended, but which fulfil the criteria of REACH Annex XI Section 1.1, be used for classification of mixtures under CLP?
- This question was very specific so not really possible to have a discussion
- It was agreed that this does need discussion following the review of the REACH Annex XI, 1.1, requirements
- Discussions with REACH Helpdesk colleagues and/or endpoint experts experienced in test reports might be beneficial.

4.4.3 Break-out group - How to deal with the classification and labelling of mixtures in soluble packaging

1) Main question:

How to classify and label soluble packaging with multiple compartments?

- The majority still consider that all compartments need to be classified individually and the classification of each compartment should be available (at least on the outer packaging).
- Most accept that the soluble packaging with the multiple compartments can be considered as one packaging (as the compartments cannot be separated), but some do not.
- If the packaging is considered as one entity, the approach of calculating a single classification by taking into account the classification and volumes of different compartments could be defended. However, some still consider that this could lead to missing some hazards that could manifest in, for example, an accident involving eye exposure.
- Most would agree to a 'Worst case' classification, where the most severe hazards from the compartments would be used.
- A 'lead component' classification approach might be useful in the case of detergents: the substances that cause both eye effects and environmental hazard are the surfactants, often present in all compartments.

Information on outer packaging

- The packaging is large and can accommodate all required information.
- Consumers do not read labels: too much information leads to 'no information', i.e. likelihood of reading the label decreases even more.
- Repetition of same information is confusing and inefficient.
- Having the hazards of each individual mixture indicated separately on the (one) label would be useful – but then the mixtures need to be easily identifiable by e.g. colour.

Information on the soluble packaging

- Is more less? Is less more? What is the appropriate level and amount of info?
- Does the presence of pictograms enhance or diminish the understanding of the hazards?
- Does the presence of pictograms increase or diminish the interest of children?
- Should there only be clear warnings? (Keep away from children!)

• Impossible to label individual compartments. The requirement for legibility would be impossible to meet. Labelling exemption of Annex I, 1.5.2.2, only applicable when point (b) is fulfilled. (And the exemption does not apply to PPPs or BPs.)

2) Secondary question:

What could be done about managing the risks posed by soluble packaging?

- Awareness raising, educating parents: education campaigns that pods really have to be kept in their original outer packaging and out of the reach of children (by industry, consumer associations etc.); recommendation for families to avoid these products if they have children under six years.
- Childproof packaging does not really exist. Most of current packages can be opened by a child (maybe not by an adult, but by a child yes...)
- It appears that children find these products similar to sweets or toys and are attracted to them. CLP Article 35(2) already allows actions by the enforcement authorities as far as it concerns the packaging.
- Restrictions related to the shape, texture, colour and form of the soluble packaging to decrease the interest of children can be considered
 - 'High pressure' pods can easily burst and cause skin and eye effects
 - Biting can puncture either whole package or just one compartment.
- Current requirement for aversive agent (bitter taste) is not fool proof as taste perception of bitter compounds is dependent on genotype and about ¼ of people do not taste these compounds.
- Definitive and reliable incident numbers can only be acquired if all MS require all units of the health care system to report them to a central body (e.g. the poison centre(s)). This is not the case at present.
- It was underlined that a discussion on potential further risk management measures falls outside the remit of HelpNet.

To conclude:

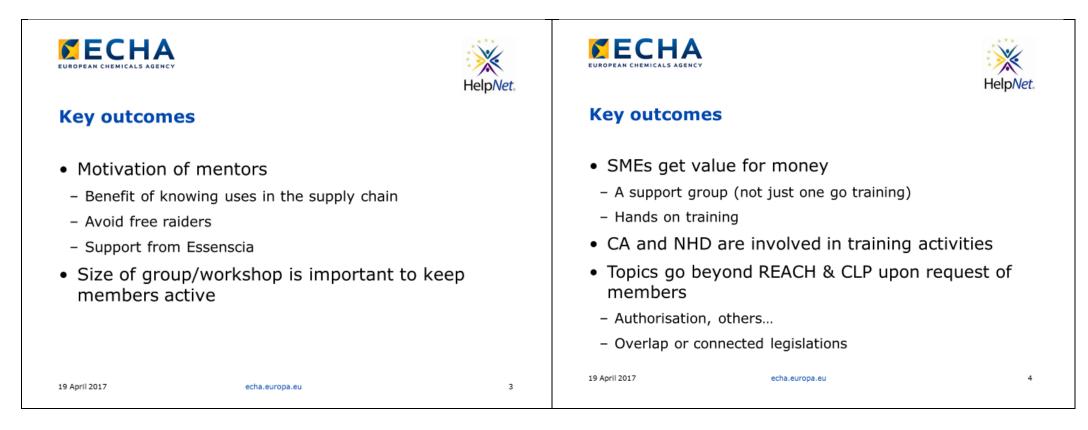
The topic cannot be concluded in the HelpNet. The views of the members differ significantly regarding the approach for the classification and labelling of the multi-compartment pods. We are aware that industry has not been able to find a common approach either. A 'worst case' classification approach could be useable – but at the moment there is no consensus on how this should be shown on the label (of either the soluble packaging or the outer packaging).

Further risk management measures should be assessed and discussed in the CARACAL. However, the Helpdesks could possibly be involved in awareness raising projects. Enforcement authorities could also consider discussing the current situation with the national helpdesks.

Annex II - Market place – summaries

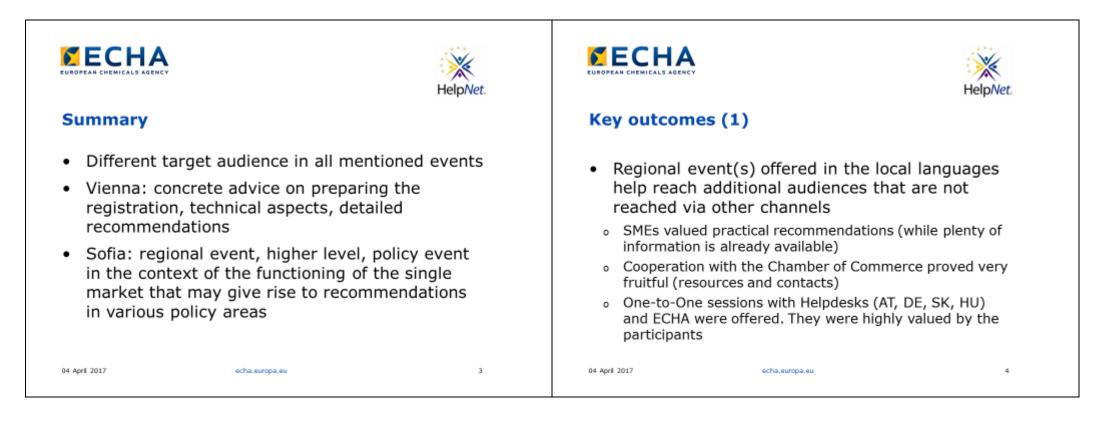
7.2.1 VLARIP & WALRIP 10 years of joining forces to implement REACH

Moderator: Tine CATTOOR, ECHA: Katarina CENDIC and Pedro ROSELLO VILARROIG



7.2.2 REACH 2018 SME workshop in Vienna (9-10 March 2017) and REACH awareness-raising event organised by the European Commission in Sofia (27-28 March 2017)

Moderators: Peter SCHINDLER (Austria) and Temenuzhka POPOVA (Commission, DG GROW) ECHA: Olena KRYCHEVSKA and Martin ALBERT





7.2.3 Tour de France seminars and REACH seminar in Cyprus

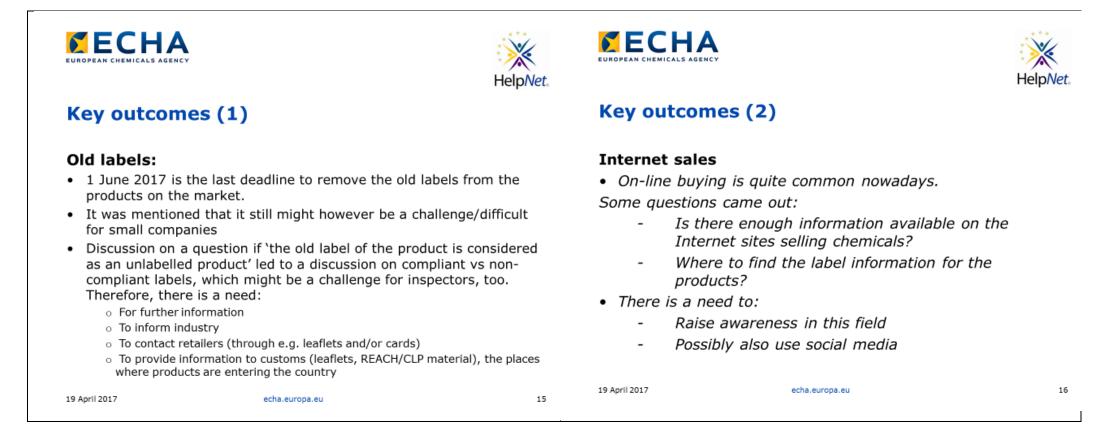
Moderators: Nathalie HAYAUD and Maria ORPHANOU ECHA: Christina LOUKOU and Guiomar SAUCEDO-CUEVAS



	HelpNet.
Remarks	
• One-to-one sessions greatly appreciate	ed
 Participants were interested in the Nat plan for SMEs by France – helpful in pr organisation of related events 	
 Enforcement authorities at customs lever increase awareness on importers 	vel can
Phone line to provide support is very u	ıseful
 Support tools: leaflets, postcards, new 	vsletters
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7.2.4 CLP-related awareness-raising activities

Moderators: Outi TUNNELA and Adam ELWAN ECHA: Anna-Liisa PIKKARAINEN







Key outcomes (3)

Chemical safety issues: to create website links to national consumer associations and work together with them.

Translations: availability of information in all the needed languages.

Some examples on campaigns already implemented in some countries:

- Website targeted at schoolchildren
- Campaign on substances of high concern, baby care products
- Videos (such as 'chemicals in life')

Unpublished information from the Commission indicating that especially some pictograms on labels are unclear to consumers.

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Action points (1)

From ECHA to NHDs. To provide:

- · Information on timelines
- Material: like leaflet(s), translations (IS, NO), the link to the video and the campaign banner 2017

From NHDs to ECHA. To provide:

- Links to relevant web pages (such as campaigns)
- Translated documents

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Action points (2)

- ECHA will send its campaign material and timelines to you (consumers/retailers)
- Helpdesks to send their campaign content to ECHA
- ECHA will provide material in your language

(additional requests for video: NO and IS)

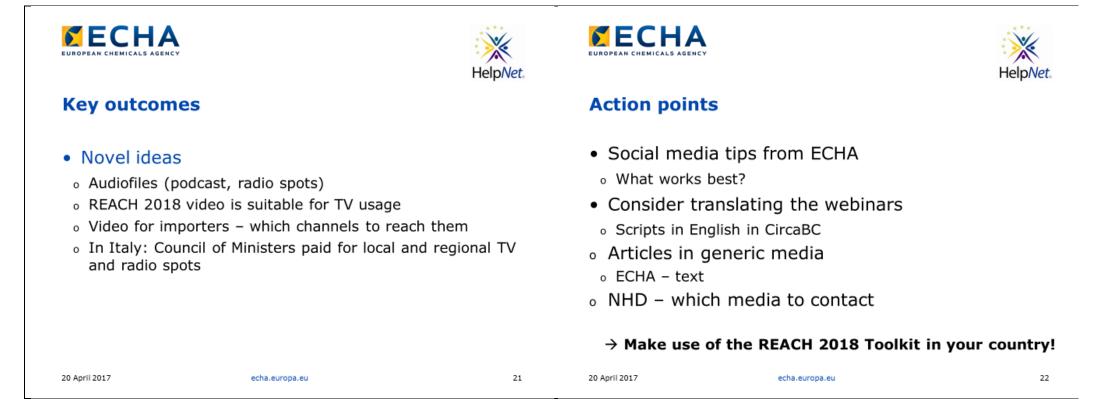
- National initiatives and materials linked in ECHA's new website for consumers (November)
- Send to ECHA your suggestions for the new site
- · ECHA will look into leaflet/poster for retailers

echa.europa.eu

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7.2.5 Feedback from Member States on the REACH toolkit

Moderator: Hanna-Kaisa TORKKELI (ECHA) ECHA: Laura WALIN and Anisa KASARUHO



Annex III - Action points

Nr	Action	A.P.	Person responsible	NHD contact	In ECHA	Due date	Status
1.	Reply to survey from the break-out group 'Questions NHDs expect in 2018' about the next ways of cooperation	3.5.2	All NHDs		HelpNet Secretariat	15 May 2017	Closed
2.	Revise HelpNet communication activities based on the feedback received from HelpNet members (e.g. frequency of HelpNet updates)	5.3			HelpNet Secretariat	By next HelpNet publication in May	Closed
3.	To have a better overview on the financial support schemes at EU level, provide feedback on national initiatives	5.7	All NHDs		HelpNet Secretariat	15 May 2017	Closed
4.	Provide feedback on national measures on promoting substitution	5.7	All NHDs		HelpNet Secretariat	15 May 2017	Closed
5.	ECHA will send material to NHDs regarding retailers to remind about the deadline of 1^{st} June 2017	7.2.4			HelpNet Secretariat, Adam Elwan	Email sent on 26 April 2017	Closed

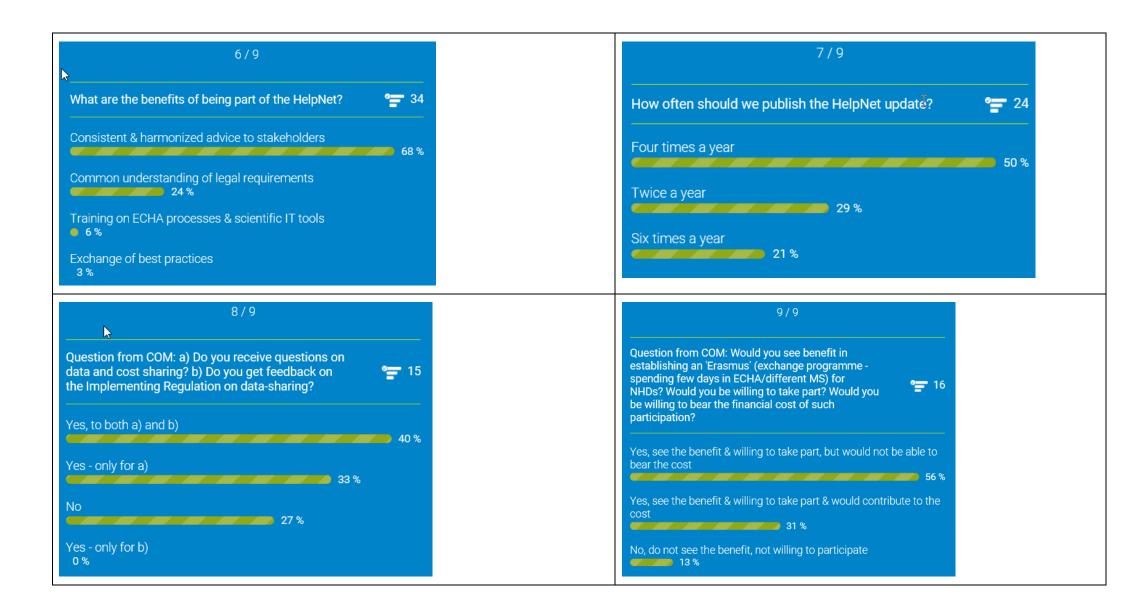
Nr	Action	A.P.	Person responsible	NHD contact	In ECHA	Due date	Status
6.	CLP video in your language. If you would like to get our CLP video in another language than the 23 EU languages, send the following texts in your language: - There are some signs you just shouldn't ignore! - Like the signs on products containing hazardous chemicals - Know the labels, stay safe: echa.europa.eu	7.2.4	Interested NHDs		Adam Elwan adam.elwan@echa. europa.eu	1 June 2017	Closed
7.	The 'names' of the pictograms To discuss with the Commission the suggestion to save on CIRCABC, in a dedicated folder, decisions related to scope issues which were discussed in HelpEx and then at CA meetings (the ones which did not go through Art.3.3)	8.6			ECHA	11-12 May 2017 (CA meeting)	Closed
8.	To analyse all the pending scope issues currently in HelpEx and decide on the most appropriate action to take: i) consult the Commission or ii) bring the issue to a CA meeting (Art.3.3)	8.6		All BPR NHDs			
9.	All owners of scope issues in HelpEx to post the final reply once it becomes available. The ultimate goal is to create a knowledgebase in HelpEx covering both scope issues and questions in ECHA's remit.	8.6		All BPR NHDs		As soon as the reply is available to the NHD	

Annex IV - SliDo reports

Link to the report: https://www2.sli.do/event/d1soesuh/infographic/c/6cd1

Interaction report from HelpNet-12 There were 89 active users	Participants sent 315 votes in 9 polls 1/9 How do you feel this morning? Genet! Looking forward to the meeting! 66% Ineed a 2nd coffee 28% Just so-so 6 %
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Annex V - List of participants

Members of HelpNet

Country	Members of He	elpNet / Advisers	IT Tools training for REACH and CLP Helpdesks	IT Tools training for BPR Helpdesks	REACH workshop	CLP workshop	HelpNet Steering Group meeting	BPR workshop
	First Name	Last Name	(21/03 am)	(21/03 pm)	(21/03 pm)	(21/03 pm)	(22/03 am)	(22/03 pm)
Austria	Stephan	LEITNER		1			1	1
Austria	Peter	SCHINDLER	1		1		1	
Belgium	Kristof	CLAES				1	1	1
Belgium	Daphné	HOYAUX	1		1		1	
Belgium	Didier	LEROY	1			1		1
Belgium	Blanca	SERRANO RAMON	1			1		
Bulgaria	Teodora	BANDAKOVA	1			1	1	
Bulgaria	Elena	TCHOBANOVA	1		1		1	
Croatia	Zdravko	LOVRIĆ	1			1	1	
Croatia	Nenad	MARINIĆ	1		1		1	
Croatia	Ivana	VRHOVAC FILIPOVIC		1			1	1
Cyprus	Maria	ORPHANOU	1		1		1	
Cyprus	Maria	PALEOMYLITOU	1			1	1	
Czech Republic	Adéla	KATRUŠÁKOVÁ	1			1	1	1
Czech Republic	Jan	KOLAR	1		1		1	
Denmark	Trine Thorup	ANDERSEN				1	1	
Denmark	Sidsel	DYEKJÆR			1		1	
Denmark	Vivi	JOHANSEN		1			1	1
Estonia	Anna	AMELKINA	1		1		1	
Estonia	Aigi	LAHE						
Estonia	Evelin	ROOP						
Finland	Hannu	MATTILA		1			1	1

1 TOLSA 1 Finland Leeni 1 1 1 Finland Sari TUHKUNEN 1 1 1 MAKI Finland Markus 1 1 France Gaëlle DUFFORT 1 1 1 1 France Nathalie HAYAUD Anja **KNIETSCH** 1 1 1 Germany 1 1 Greece Dimitrios CHATZIANTONIOU 1 1 1 1 Greece Panagiota SKAFIDA 1 1 1 Greece Vasileios VAGIAS 1 1 Eszter HARSANYI 1 Hungary 1 1 1 Viktor Péter NYITRAI Hungary SZÁNTÓ 1 1 1 Hungary Emese Ísak Sigurjón 1 Iceland BRAGASON 1 1 1 1 1 Iceland ODDSSON Einar 1 1 1 Ireland Caroline WALSH D'ILIO 1 1 1 Italy Sonia 1 1 1 Italy Francesca GIANNOTTI 1 1 1 Latvia Natāliia JAUNKALNE Latvia Liga RUBENE 1 1 1 1 VZESNIAUSKAITE 1 1 Evelina Lithuania PIPIRAITĖ-1 1 1 VALIŠKIENĖ Lithuania Donata ŽIRGULEVIČIŪTĖ Žiedūna 1 1 1 Lithuania 1 1 Luxembourg Laurene CHOCHOIS 1 1 HEINEVETTER 1 1 Luxembourg Anna-Lisa 1 1 1 ZIGRAND Luxembourg Jeff 1 1 1 1 Malta Wayne GIORDMAINA 1 1 1 Eveline Tatjana 1 Netherlands BEIJ 1 1 1 Netherlands Margaretha WOUTERS 1 Norway Suzanne GORDON 1 1 1 LARSEN 1 Norway Ann Kristin 1 1 Norway Marianne **TVERMYR**

Poland	Renata	KAMIŃSKA		1			1	1
Portugal	Maria de Fátima	ARAÚJO	1		1		1	
Portugal	Inês	MARTINS DE ALMEIDA		1			1	1
Portugal	João	PIMENTEL	1			1	1	
Romania	Nicoleta	CAROLE	1			1	1	
Serbia	Jelena	GRUJIC	1	1			1	1
Serbia	Aleksandra	RASOVIC	1			1	1	
Slovakia	Martina	DANIHELOVÁ	1		1		1	
Slovakia	Michal	PORUBIAK	1			1	1	
Slovakia	Mária	ŠKULTÉTYOVÁ		1			1	1
Slovenia	Tatjana	HUMAR JURIČ	1			1	1	
Slovenia	Anja	MENARD SRPČIČ	1		1		1	
Slovenia	Marta	PAVLIČ ČUK		1			1	1
Spain	Maria Aranzazu	LOPEZ FRANCO		1			1	1
Spain	Maria Elena	SANCHEZ DIAZ	1			1	1	
Spain	Laura	ZAMORA NAVAS	1		1		1	
Sweden	Åsa	ALMKVIST		1				1
Sweden	Jonas	FALCK				1	1	
Sweden	Helena	KRAMER	1		1			
Sweden	Anneli	RUDSTRÖM		1			1	1
Sweden	Jenny Sophie	VIRDARSON	1		1		1	
UK	David	LAU		1			1	1
UK	James	LLOYD	1		1		1	

Organisation / Country	Stakeholders/Observers		IT Tools training for REACH and CLP Helpdesks	IT Tools training for BPR Helpdesks	REACH workshop	CLP workshop	HelpNet Steering Group meeting	BPR workshop
-	First Name	Last Name	(21/03 am)	(21/03 pm)	(21/03 pm)	(21/03 pm)	(22/03 am)	(22/03 pm)
Essenscia, Belgium	Tine	CATTOOR					1	
IMA-Europe, Belgium	Celia	GRYSPEIRT				1		
CEPE, Belgium	Didier	LEROY	1			1		1
CEFIC, Belgium	Blanca	SERRANO RAMON	1			1		
Only Representatives Organisation, Belgium/ Ireland	Kevin	HOBAN	1		1		1	
A.I.S.E., Belgium/ Netherlands	Gerardus	LUIJKX				1	1	
Ministry of Agriculture and Environmental Protection, Serbia	Jelena	GRUJIC	1	1			1	1
Ministry of Agriculture and Environmental Protection, Serbia	Aleksandra	RASOVIC	1			1	1	
Swiss Notification Authority for Chemicals, Switzerland	Olivier	BLASER		1			1	1
Istanbul Minerals and Metals Exporters Association, Turkey	Mutlu	DEMIRKAN	1		1		1	
Istanbul Minerals and Metals Exporters Association, Turkey	Pinar	ÖZGÜN	1			1	1	1

Stakeholders/Observers of HelpNet

European Commission

European Commission (by videoconference*)	First name	Last name	IT Tools training for REACH and CLP Helpdesks (21/03 am)	IT Tools training for BPR Helpdesks (21/03 pm)	REACH workshop (21/03 pm)	CLP workshop (21/03 pm)	HelpNet Steering Group meeting (22/03 am)	BPR worksho p (22/03 pm)
DG GROW	Temenuzhka	POPOVA	1		1		1	
DG GROW	Maurits-Jan	PRINZ				1	1	
DG SANTE	Martinus	NAGTZAAM*						1
DG SANTE	Pilar	CASADO DE AMEZUA*						1
DG SANTE	Alfonso	LAS HERAS*						1

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