

HelpNet REACH workshop: summary of discussions

Time Tuesday 17 November 2015, 09:00 – 18:00 Wednesday 18 November 2015, 09:00 – 14:15

Place European Chemicals Agency

Annankatu 18, 00120 Helsinki, Finland

The HelpNet REACH workshop, organised for the HelpNet REACH members and observers (see Annex I for list of participants), took place during two days on 17-18 November 2015. The first day was dedicated to substance identification, while the second day focused on timely REACH topics. The first day was chaired by Jos Mossink, Head of Unit Substance ID & Data Sharing Unit, and the second day by Johan Nouwen, Head of Unit Support, Forum and HelpNet Secretariat. This document summarises the ideas discussed and agreed conclusions. Please note that the text of the REACH Regulation is the only authentic legal reference and that this workshop summary does not constitute legal advice. For further advice contact your national REACH helpdesk.

Tuesday 17 November 2015 - Substance identification

The Chair of the first day of the workshop, **Jos Mossink** (Head of Unit Substance ID & Data Sharing Unit) welcomed the workshop participants.

Opening of the workshop

Christel Musset, Director of Registration, introduced the HelpNet REACH workshop. The agenda of the workshop was developed based on the feedback received from the HelpNet members and on issues which ECHA identified as particularly relevant for providing consistent and harmonised helpdesk advice and support towards the 2018 registration deadline, in particular to SMEs. The goal of the workshop is to provide a strong support network to companies, ensure efficient information exchange among HelpNet members, encourage active participation and sharing of ideas, and to receive feedback on ECHA's activities.

It was specified that:

- The first day focuses on Substance Identity (SID), providing an overview of the latest developments on SID and ECHA's new service on the change of chemical identifiers in registration dossiers. These presentations will be followed by interactive world café and breakout group sessions with a view to exchange experience and share best practice on SID 'hot' topics.
- The second day is devoted to the REACH 2018 registration roadmap and other topical issues, providing an update on the changes in the registration process, review of Phase 2 & 3 related FAQs, broadcasting of Phase 2 webinar and the opportunity to discuss in world café sessions. Other topical issues include an update on the Court Ruling on substances in articles, the state of play of the HelpNet working group on downstream user support, activities of ECHA and MS on substitution, and discussions on HelpEx questions.

A participant enquired about the current estimations regarding the expected number of substances to be registered in the 2018 deadline. ECHA explained that the impact assessment revealed a figure of 65,000 dossiers. However, the number of intermediate dossiers may be overestimated. The large companies are being surveyed first and some realistic estimates of the figures are expected in February 2016.

1. Substance Identity

1.1. Update from ECHA on substance identity

Steven Buchanan (Substance ID & Data Sharing Unit) briefed the participants regarding the **latest updates on substance identification**. These involve, amongst others, the review of the SID webpages, revision of SID Q&As, publication of an ECHA newsletter article on analytical data requirements, SME workshops and visits, update of IT tools and manuals, and sector-specific support (oleochemicals, essential oils, hydrocarbon solvents, complex inorganic pigments) webpages and guidance (partly in collaboration with OECD). Additionally, SID-related projects include: the SIDC (COM) project on the analysis of complex substances (outcome to be presented at HelpNet 11) and the PetCo project for the development of a risk management approach for petroleum and coal substances.

A participant pointed out the usefulness of the sector-specific support and suggested that it would be very beneficial to develop guidelines for petroleum substances, for importers of mixtures with respect to the analytical data requirements, as well as for the identification of recovered substances. Another participant also added the need for guidelines for importers of polymers regarding analytical data. ECHA replied that there is currently collaboration between ECHA and CONCAWE regarding petroleum substances. For importers of mixtures some guidelines are under development and this issue is also addressed in the Newsletter article on analytical data (ECHA Newsletter - June 2015 issue: http://newsletter.echa.europa.eu/home/newsletter/entry/3 15 get-your-substance-identity-right-heres-how). Regarding the recovered substances, the need has already been identified and the NHDs are invited to highlight additional sectors for which support is needed.

Regarding ECHA's SME visits, a participant asked how easy it was to get volunteers from the different MS. ECHA replied that it depended on the country; in larger MS it was easier to find SME volunteers. ECHA's SME visits are performed in the language of the specific country and more visits were planned until the end of November 2015.

1.2. SID adaptation service

Risto Linna (Substance ID & Data Sharing Unit) presented ECHA's new **service for the adaptation of the main identifiers** of a registered substance. This administrative service, which occurs at a small charge, can be used by registrants to correct or refine the identity of their substance, either on their own initiative or following a compliance check by ECHA. In order to request this service, certain substance identification information needs to be provided by the registrant, including documentary evidence to demonstrate that the new chemical identifier is for the substance originally intended to be registered.

A participant questioned why, since the technical limitations do not allow the registrants to update their data, ECHA's IT systems are not updated instead of putting in place this service. Additionally, it was asked what happens when the change involves a very different substance. ECHA replied that, by establishing this service, ECHA is in control to assess whether the company can demonstrate that the new identifiers correspond indeed to the substance which was intended to be covered. In that way, ECHA avoids that companies randomly change the ID of their substance and can decide to refuse the service, if it is not applicable.

Another participant asked how the change of identifiers occurs practically and why the charge (300 euros) is necessary, particularly for SMEs. It was explained that ECHA facilitates the process by preparing the IT system and enabling the change in the Joint submission object after which point the registrant can then update their dossier. It was also noted that the charge for the SID adaptation service is set by an ECHA's Management Board decision. Since it is a service beyond the legal requirements, a minimal charge needs to be put in place to reflect

the administrative work required. Nevertheless, the actual work by ECHA surpasses the charges imposed to the registrant.

A participant asked whether a company has legal obligations to request the service if ECHA finds under CCH that the identifiers of their registered substance are incorrect. Additionally, the implications within a SIEF were questioned in case different registrants within the same SIEF have different identifiers. ECHA agreed that the communication of member registrants with the lead registrant may be challenging. So far, only different opinions have been expressed within a SIEF but LRs are mostly cooperative. It was also added that it might be possible for certain registrants to change e.g. to 'substance A' and for others to change to 'substance B'. In such cases a possible scenario would be to split the joint submission into two different joint submissions.

On the same issue, another participant pointed out that if the SIEF cannot agree on the same substance and the joint submission is split, this is not only affecting a SID change; QSARs will need to be made for the second substance. ECHA explained that the SID adaptation service facilitates the discussions within the SIEF to reconsider the data available in a dossier.

A participant asked whether the company has to agree within the SIEF to split the joint submission and then contact ECHA. She also asked if the charge (300 euros) for this service applies to each registrant. ECHA confirmed both points.

2. World café session on providing support to companies

2.1. What type of questions do the NHDs receive on substance identity?

Nuria Puigpinos (Substance ID & Data Sharing Unit) chaired a discussion with the participants on the most frequent topics the national helpdesks (NHDs) receive and the topics they consider complex. The discussion was focused on the way NHDs approach difficult questions, the ECHA support material most frequently used (and any support material developed by the NHDs) and the identification of SID topic areas for which further support is needed.

The discussions showed that SID questions are not among the frequently received questions of many of the NHDs. Also, if the NHDs receive difficult SID questions, they advise the companies to contact ECHA. Some common SID questions that the NHD receive relate to substance types, analytical methods, level of analytical requirements, Annex V exemptions, substances of natural origin and issues with chemical identifiers. Complex topics include mainly the analytical requirements for importers of mixtures and polymers, identification of recovered substances and sameness of UVCBs. ECHA receives frequently questions on the following 'hot' and often complex topics: UVCB sameness, polymers/monomers, Annex IV and V exemptions, use of additives/ solvents, intermediates, hydrates, deviations from the Guidance rules, forms of a substance, by-products/ waste/ recovered substances, stereochemistry issues, analytical methods.

2.2. Sector-specific support

Helene Jardin and **Ronan Nicolas** (Substance ID & Data Sharing Unit) moderated a discussion on the sector-specific guidance on SID which is currently available, or under preparation, and the needs of industry for further sector-specific support.

In the context of REACH Roadmap 2018, ECHA has contributed in the preparation of the guidance on essential oils in collaboration with the European Federation of Essential Oils (EFEO) and the International Fragrance Association (IFRA). A guidance on complex inorganic pigments is also currently under development. In addition, in collaboration with OECD, two guidance documents, on oleochemicals and on hydrocarbon solvents have been made

available. These guidance documents should be considered as complementary to the official Guidance on SID, expanding further on the general concepts to ensure a consistent approach on SID within each industry sector. Links to these documents and useful information are available under the new dedicated webpages on sector-specific guidance, at: http://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification.

The NHDs expressed the need for development of sector-specific guidelines on petroleum substances, substances recovered from waste, import of mixtures and polymers, UVCB sameness and the interpretation of the scope of Annex IV & V exemptions.

2.3. SID support material under the REACH roadmap

Steven Buchanan (Substance ID & Data Sharing Unit) presented the SID support material developed by ECHA under the REACH roadmap and requested feedback by the participants. ECHA's webpage content on SID has been improved and it now includes:

- Improved webpage on SID under the Regulations section: http://echa.europa.eu/regulations/reach/substance-identity
- An additional webpage on SID support under the Registration Support section: http://echa.europa.eu/support/substance-identification
- Dedicated webpages on sector-specific support (sub-page): http://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification

The participants provided positive feedback on the new support material, of which not all participants were aware of. Raising awareness of the new material was considered important. Many of the NHDs refer to ECHA's support material on SID and do not have dedicated SID webpages on their national websites. DE and FI mentioned that they have developed a note/factsheet on SID.

3. Break-out groups - first session

The breakout group sessions involved discussions on SID 'hot' topics. The purpose of the sessions was to receive feedback on how NHDs approach complex questions, identify needs for additional support material on SID, collect ideas on how to improve collaboration and sharing of information on SID issues and ensure common interpretation and harmonisation of replies to SID questions.

3.1. Substance sameness

Ronan Nicolas (Substance ID & Data Sharing Unit) highlighted that the topic of **substance sameness** is relevant for all processes under REACH and CLP in terms of joint registrations, data sharing, recovered substances, Annex IV and V exemptions and SVHC (substances of very high concern) entries in the Candidate list. While criteria have been clearly set for well-defined substances in the Guidance on SID, for UVCB (Unknown, or variable composition, or of biological origin) substances substance sameness is more difficult to ascertain and several sector-specific challenges are encountered. The discussion was centred around examples provided on sameness under registration (inquiry/data sharing, joint submission, Substance Identity Profile (SIP), recovered substances) and sameness with regard to an SVHC entry in the Candidate list.

The participants indicated that they receive a limited number of questions on substance sameness, mainly related to Annex IV and V exemptions (e.g. substances of natural origin, byproducts) and recovered substances. Since these questions are rather specific, they are addressed on a case-by-case basis by making reference to the substance sameness criteria set out in Chapter 5 of the Guidance on SID. It was highlighted that substance sameness should

be based on the composition and, if relevant, on the manufacturing process and source (UVCBs); hazardous properties and impurity profile should not have an impact on substance identification. Additionally, ECHA indicated SIP as an upcoming 'hot' topic, despite the fact that no related questions have been received so far by the NHD. Regarding sameness with respect to an SVHC entry in the Candidate list, it was pointed out that harmonisation of the interpretation of what is covered under certain group entries in the Candidate list is necessary due to the respective legal obligations (also those related to Annex XIV and XVII). ECHA has started creating notes, in addition to the supporting documents of certain group entries, to clarify further the scope of such generic entries. Furthermore, it was noted that sharing of the replies to sameness questions with the NHD would be beneficial.

3.2. Annex IV and V exemptions

Michal Skowron (Substance ID & Data Sharing Unit) pointed out that ECHA receives very frequently SID-related questions on **Annex IV and V exemptions**. Few questions are received on Annex IV entries, related to the broad entries defined by EINECS descriptions, while, a larger number of questions are received on Annex V entries; these are mostly related to substances of natural origin (and their chemical modification), hydrates and by-products. In order to illustrate the complexities arising from such questions on the scope of Annex IV and V exemptions, several examples were presented for discussion (Annex IV: "syrups, hydrolysed starch"; Annex V: "decanoic acid", "biogas", "natural bitumen", Annexes IV/V: "reaction mass of nitrogen and hydrogen").

It was concluded that both NHD and ECHA have a similar interpretation of the scope of Annex IV and V entries. As a starting point, the NHD rely on ECHA's Guidance on Annex V, which provides detailed information on the scope of each of these entries. In case of doubt, the NHD usually contact ECHA, the MSCAs, enforcement or other technical agencies. Enquiries received by the NHD on other entries than the examples presented, include questions on glass (Entry 11), glycerol/ soaps/ lauryl sulfate imported from recovered substances, hydrates (Entry 9) and gypsum. Regarding the example on the "reaction mass of nitrogen and hydrogen", it was highlighted that the exemptions refer to substances and not to individual constituents of a substance, therefore registration obligations apply to this multi-constituent substance. Lastly, issues related to the registration obligations (or possible exemption) in the case of charcoal were brought forward and the need for further information from COM and an FAQ was highlighted.

4. Break-out groups - second session

4.1. Forms of a substance

Pawel Figiel (Substance ID & Data Sharing Unit) introduced the concept of the **"form" of a substance** as the specific composition of a substance that has a morphology characteristic (e.g. ingot, powder, fibre, nanoform), a characteriser (e.g. crystal phase of inorganics, chemical surface treatment of nanoforms) or differing hydration states (e.g. anhydrous, hydrates) that impact properties relevant for hazard assessment. A substance may have different "forms" which can be registered together as different grades of the same substance. Nevertheless, all forms (grades) of the substance need to be considered in terms of the information requirements in Annexes VII-XI. Key issues to consider are the obligations and roles related to the change of a form of a substance and whether this activity should be regarded as a manufacture or downstream use. An example based on a HelpEx question (HELPEX 12111) on the purification of technical ethanol was presented to highlight these issues.

Bernadette Quinn (Substance ID & Data Sharing Unit) provided a clarification on the FAQ 38 on the exemption from registration for chemically surface treated substances. There is an agreement at MSCA, ECHA and COM level that this exemption does not apply to **surface treated nanoforms**, which should be reported as different compositions of the corresponding

registered substance. Registrants have, nevertheless, applied the FAQ 38 and considered the surface treatment activity as "use". Several examples from experience through implementation in ECHA's Evaluation processes were presented (e.g. silicon dioxide, titanium dioxide, sodium aluminium silicate) and it was pointed out that this has resulted in seven Appeals to date.

Tuomas Aitasalo (Substance ID & Data Sharing Unit) gave an overview on **catalysts** and the related registration obligations. Inorganic catalysts are regarded as mixtures and, accordingly, their individual components should be registered separately. This raises some questions, since organometallic catalysts also exist (such as Ziegler-Natta catalysts), which, in principle, should be registered. Nevertheless, no registrations of catalysts as substances in their own right have been received so far. Another common issue is that related to the registration obligation applying to catalyst precursors (possible intermediates) since it needs to be defined at which point in the manufacturing process they are converted into the corresponding catalysts.

The NHD have not received any questions and have little experience regarding "forms" of a substance, catalysts or surface treatment. Some questions have been received related to purification processes, hydrates and crystalline forms. A key issue that emerged from this discussion was the difficulty in identifying whether an activity is a manufacture or a downstream use and this has, consequently, an impact on the related obligations. Upon discussion of the example case on the purification of technical ethanol, it was highlighted that if a purification process results in a change of the qualitative composition of the substance, then these different form(s) can be registered together as different qualities/ properties of the same substance. It was mentioned that the SIP would be a good tool to justify why substances should be registered together. Regarding nanoforms, they have been reported so far only in 11 dossiers, possibly owing to obligations not being so clear, and the negative public perception on nanomaterials. As for catalysts, the absence of registration dossiers might be due to misinterpretation of related obligations, confidential business information related to their manufacturing process, or low tonnage of manufacture or import (below 100 t/y). It was concluded that such complex questions could be discussed with enforcement or shared for discussion (or for information) in HelpEx.

4.2. How to address missing analytical data

Laszlo Majoros and **Ronan Nicolas** (Substance ID & Data Sharing Unit) demonstrated the issue of **missing analytical data** on registration dossiers by referring to the example of polymers and monomers. Polymers are exempt under REACH but registration obligations apply to the monomer substance(s) and any other substance(s) covalently bound to the polymer. Analytical data on the monomer substance, when not available, needs to be obtained by requests up the supply chain which are often unsuccessful. This obliges many companies to buy the laboratory standards corresponding to their monomer substances and generate the analysis on those pure chemicals, despite them not being used in the polymerisation process. A further complication arises when monomer substances are possible CMRs, which creates problems with the handling of such substances during analysis. In order to illustrate such difficulties related to obtaining analytical data for the monomers and the handling of hazardous substances, two example cases of monomer registrations (e.g. PVC, ethylene oxide) were presented.

The discussion focused on alternative approaches when the analytical data on the monomer is not available despite several requests up the supply chain. In such cases, the possibility to switch to another supplier willing to be compliant with REACH, or to appoint an only representative was discussed. As a last resort, if all attempts to obtain this information fail, providing proof of communication up the supply chain, together with data on the polymer which can qualitatively prove the presence of the monomer in the polymer could be acceptable as an alternative. Nevertheless, since one monomer registration could lead to the import of many different polymers, it is difficult to conclude on which polymer to analyse to back up the monomer registration. It was noted that it would be useful to establish a list of available analytical techniques for the characterisation of monomers and polymers. Additionally, the

possibility of waiving of certain analytical data in case of substances with hazardous properties was discussed. Finally it was concluded that any deviations/ waiving from the standard requirements will need to have legal assessment and CARACAL approval. Sector-specific associations could be an additional source of information. Such alternative approaches could also be discussed by the Forum in order to agree on proposed strategies.

Closing of the day

The participants expressed their satisfaction in the fruitful discussions of the day and clear messages given by ECHA on substance identity. It was acknowledged that even though currently NHDs may not be receiving such high numbers of substance identity questions, they should be the ones aware of the topic and agreeing on harmonised replies. In order to enforce both knowledge building and common views on the topic, it was agreed that ECHA will start providing replies that it has given to companies on HelpEx for a basis for discussion. The NHDs are encouraged to do the same.

It seems that many of the questions that are difficult to answer are those where reading the guidance as such does not help. Coming to a simplistic approach is often not possible, or at least not easy. It was highlighted that discussions with industry associations are important to see what in practice the companies could be doing to ensure they fulfil the REACH requirements.

It was also mentioned that on some topics ECHA and the NHDs have differing views, as has been demonstrated in some HelpEx discussions. It is important to achieve clear understanding on such topics. On FAQs, it was also highlighted that FAQ criteria should not only apply to questions that are asked frequently but which are important. ECHA and NHDs can consider proposing FAQs for topics identified in the break-out groups.

Wednesday 18 November 2015 - Hot topics on REACH

5. Latest updates from ECHA

5.1. Court of Justice judgement on substances in articles

Theodora Basmatzi (Legal Affairs Unit) gave an overview of the REACH requirements for substances in articles, background of the judgement and the meaning of the judgement. She also informed of the next steps related to the update of the ECHA's guidance on Substances in Articles and related Q&As and FAQs.

A HelpNet member asked whether ECHA could make available on its website the guidance prepared by other Member States at least for the transitional period. ECHA clarified that it will take the guidance into account when revising its guidance. Another member asked how enforcement will consider the ruling and how can they enforce without a guidance document. ECHA responded by saying that the issue is within the remit of Forum, which has discussed the topic in its November meeting. Forum is of the opinion that the Member States who had dissenting views are already enforcing accordingly. Enforceability is not dependent on the existence of a guidance document.

5.2. Changes in the registration process

Javier Sanchez-Saez (Dossier submission & PIC Unit, ECHA) gave an overview of the drivers of change to the registration process and the main changes to be implemented. These include the 'one substance, one registration principle' (OSOR principle), revised completeness check, updated support material and changes in the IT tools (IUCLID 6, Chesar 3 and REACH-IT).

For related discussions, see agenda item 6.2.

6. REACH Roadmap 2018 and Downstream User support

World café session

6.1. Review of Phase 2 and 3 related FAQs

Maia Sokolova (Support, Forum and HelpNet Secretariat, ECHA). The group discussed the general criteria for reviewing the FAQs and in particular related to Phase 2 and Phase 3 of the REACH Roadmap 2018. The review of these FAQs is not very straightforward as many of them are related to IT tools, which are currently being revised. Similarly, many of them have touched upon data sharing and they were developed when no related guidance was available. As now there is specific data sharing guidance available as well as other support materials, and on the other hand the implementing regulation on data sharing is upcoming, many of the FAQs may no longer be needed.

During the discussions it was generally agreed that it is important to have FAQs which are of value. If the content is well covered by guidance documents and webpages, or the FAQs are highly technical, related to the use of IT tools, such FAQs can be revoked. There is no need to have FAQs which are "of general nature" or are covered elsewhere.

Also, the simplification of language was seen as important. The discussions also touched upon ECHA's Q&A Support and how FAQs are presented there. It was agreed that FAQs do not need to be called FAQs (compared to the other Q&As) as long as it is visible that these Q&As have been agreed among NHDs, ECHA and the European Commission.

6.2. Changes in the registration process - Q&A

Javier Sanchez-Saez (Dossier submission & PIC Unit, ECHA), **Mercedes Viñas** (Computational Assessment & Dissemination Unit, ECHA). During the discussions, the need to raise awareness of the changes in the registration process was raised. ECHA counts on NHDs to support it in this work. With a large number of (new) companies registering for the 2018 deadline it was considered important that NHDs gain capacity to reply to general questions on IT tools, whereas more complex technical issues can be forwarded to ECHA. The need for hands on training for the NHD was expressed, including IUCLID, REACH-IT, the Completeness check, and the "One substance, one registration" OSOR principle (Joint submission).

The importance of having a direct contact between ECHA and NHDs was also highlighted, which can be achieved e.g. by regular exchange of main incidents to share knowledge. The need for access to a REACH-IT test environment to be able to support customers (support material, simulate situations reported) was also mentioned.

ECHA informed that a IUCLID 6 desktop test version is available as of 20 November (request it at iuclid6.echa.europa.eu). All changes in the registration process will take effect when REACH-IT goes live; tentatively at end of May 2016.

The following aspects were also raised:

- Help manuals will be integrated into IT systems and translated into all EU languages;
- Basic information package on main changes in IT tools and registration process would be helpful;
- All existing data (REACH-IT, IUCLID) will be migrated to the new version;
- For 2018 Roadmap: suggestion for a checklist of basic skills to be able to complete a registration.

6.3. Keeping each other aware of relevant issues for each phase of the REACH 2018 Roadmap

Laura Walin (Registration Directorate). ECHA announced the timetable for 2016 for launching the phases 3-6 of the REACH 2018 Roadmap as follows (the first day refers to the publication of new support material, the second day to the date of the webinar of the phase):

- Phase 3: 1-2 March 2016;
- Phase 4: 19-20 July 2016;
- Phase 5: 3-4 October 2016;
- Phase 6: 29-30 November 2016.

The HelpNet participants were asked to share their 2018 related plans. Many NHDs confirmed that registration 2018 does not seem to be on the agenda of the companies yet, at least based on the fact that the helpdesks do not receive questions on it. The only questions received are of a more strategic nature: how long a company can stay on the market without registering the substance, and whether the stocks can be put on the market even after the registration deadline. It had also been asked how late is it possible to decide/start the preparations, and whether it is expected that there will be a shortage of laboratory capacity. It is also clear that companies are not yet subscribing to events where REACH 2018 is a topic, at least not to the extent expected by the authorities. This concerns especially SMEs.

It was suggested not to market these events as "REACH 2018 events" but rather events on "chemical safety awareness" to attract more participants.

Awareness raising activities

Many countries have already reached out or are planning to reach out to the pre-registrants in their country. It was discussed whether it would be useful if ECHA also contacted the pre-registrants for awareness raising purposes. It was concluded that it might be a good idea to reinforce the message of getting started. However, in countries where the national authority has already contacted the companies, the ECHA message should refer to the national message so as not confuse the recipients. It was noted that sending the emails (as picked from REACH-IT) reveals also how up-to-date companies REACH-IT contact details are. It was noted that inspectors should carry the REACH 2018 message to companies. The generic leaflet done in the REACH 2018 Communicators' Network is fit for this purpose.

Communication products

The special e-News on different phases was appreciated as a good information package. However, it was mentioned that an intro to the REACH registration is missing. It was suggested that ECHA would provide the generic leaflet also in the form of an email that could be forwarded by different multipliers to their own contacts. There was a common view that companies, especially SMEs would need more practical advice on registration. This concerns especially the time and resources needed to prepare a registration and the approximate cost of it. ECHA website is in general still very complex for an inexperienced user to approach. ECHA explained that changes may happen in 2016 as there is an on-going customer insight survey. Once the companies find the REACH 2018 pages, it is easier for them to navigate. Therefore, a lot of effort needs to be put into promoting the starting page (http://echa.europa.eu/reach-2018) as the one-stop-shop for REACH 2018 information. ECHA informed that it is also planning to add a page for information in national languages to the REACH 2018 pages, linking to known REACH 2018 pages e.g. on MSCA websites.

6.4. HelpNet WG on Downstream User support: state of play & next steps

Bridget Ginnity and Andrew Murray (Risk Management Implementation Unit).

The objective was to explore how HelpNet can develop and share support materials for downstream users (DUs) between member states and to explore how member states and HelpNet can help companies to integrate REACH obligations with those under other chemicals legislation. Two questions were addressed:

Question 1:Member states could co-develop and share support materials for downstream users. What are the benefits and drawbacks of this? What could we all do to make this happen?

The participants expressed their satisfaction with the support material that is provided by ECHA (eGuide, webpages etc). The difficulty is reaching out to DUs not within their normal catchment group. For new material, the greatest need is for newcomers, to get a quick overview and know where to start.

Sharing material among NHDs was supported, but considered hard to make it happen. The participants suggested having a platform (coordinated by ECHA) to "post" information including more opportunity to describe developments in HelpNet meetings forming working groups (as happened with EHS group and SME group). Also HelpNet meetings could be used for this purpose. The participants also identified a need for themselves to be up-to-date with developments from the Exchange Network on Exposure Scenarios (ENES).

Question 2: Users of chemicals often get advice on obligations from REACH/CLP without reference to other chemicals legislation. Has HelpNet a role in bridging this gap? What can

member states and HelpNet do to help bridge this gap?

The participants recognised the need and the potential benefits but most NHDs have a clearly defined scope, and it is difficult to integrate more with other legislation/authorities. The NHD direct companies to the source of information but cannot provide a coordinated response, or proactively provide integrated advice/guidance.

Experience has been that even broadening the title of what NHDs do can help (e.g. instead of a seminar on REACH/CLP, advertise a seminar for safe use of chemicals). Some NHDs provide decision trees which deal with all legislations. Several participants suggested that it is more the role of sector organisations to provide integrated advice. The EEN has been a useful partner is some instances.

Broadcast of the REACH Roadmap 2018 Phase 2 Webinar

The participants followed the REACH Roadmap Phase 2 Webinar.

7. Substitution

7.1. Activities on substitution: ECHA, Member States

Denis Mottet (Risk Management Implementation Unit) presented ECHA's substitution activities. These included ECHA's current projects on substitution, such as "Improving the Analysis of Alternatives and practical ways of promoting innovation and substitution in the EU", ECHA's new web pages on substitution, and a dedicated webinar series on substitution. NHD were encouraged to contact ECHA on related collaboration initiatives and also indicate the need for further support or training. Jean-Marc Brignon (Head of Economics and Decision Tools, INERIS) and **Lothar Lissner** (Managing Director, Kooperationsstelle Hamburg IFE) participated through a video conference and presented a thought starter on a tool to support substitution for REACH. The presenters provided an overview of lessons learnt from past experience, highlighted the need for practical and scientific support and advice on substitution, and introduced the proposal for a targeted portal for REACH which would provide e.g. a "registry" of substitution, reporting on case studies and alternative chemicals, and a rolling list of a constant and manageable number of chemicals. Main open questions, including the need to provide training and/or substitution tools, and the extent of checking or validation of information from enterprises were discussed. The presenters requested feedback and indications for intentions to participate in the project.

The participants considered the initiative very interesting. A participant noted that currently it is not possible to search by substance on the ECHA's website and to know under what process a substance is. If companies could be warned at a very early stage on what might happen to their substance, they could start thinking about substitution as the next step. Also, financial tools on substitution could be made more visible on ECHA's website and included in related communication. ECHA clarified that much information is available on its website, and e.g. when searching for a chemical identity, you also see whether it is included in Annex IV etc. ECHA is aware of the current limitations, and a new way of disseminating information will be launched in 2016.

INERIS encouraged Member States to investigate their possibility of being involved in the project proposal, and to communicate directly to Mr Brignon as this was not an ECHA project. A HelpNet member asked whether the assessment of alternatives is available in the substitution portal as Member States need to support those who are preparing Annex XV dossiers. It was clarified that the goal of the project is to provide such information already at an earlier stage of the restriction process.

8. HelpEx questions

Peter Megaw, Outi Tunnela (Support, Forum and HelpNet Secretariat, ECHA)

8.1. HelpEx 12815

It was clarified that a supplier of a substance/mixture that has compiled and provided to their customers an SDS in compliance with Regulation (EU) 453/2010 before 1 June 2015 can benefit from the transitional period until 31 May 2017 provided in Article 2 of Regulation (EU) 2015/830, both where:

- 1. New supplies of the substance/mixture to previous recipients made after 1 June 2015 and
- 2. Supplies to new customers who bought the substance/mixture after 1 June 2015, provided that there is no need for an update according to Article 31 (9) of REACH.

Article 2 of Regulation (EU) 2015/830 does not define the time of delivery of the substance/mixture or whether the supply is to new or previous recipients. Thus SDSs in compliance with Regulation (EU) 453/2010 (either Annex I or Annex II), provided to any recipient at least once before 1 June 2015 may continue to be used until 31 May 2017, if there is no need for update according to Article 31 (9) of REACH.

8.2. HelpEx 12350

The issue of whether the contact details of the supplier must always be included in the SDS has been open for a long time. The question is still very relevant. It was decided that the question should one more time be clarified with the Commission. ECHA would draft a paper to for comments.

Closing of the workshop

The Chair closed the second day of the workshop by praising the participants for their active participation and valuable contribution to the discussions and by summarising some of the main messages of the day:

- NHD need to be trained on the registration process and new IT tools so that they can support companies on related questions. Difficult IT tools questions will nevertheless be resolved by ECHA;
- Awareness raising on REACH 2018 remains a big issue as companies are not yet preparing. When organising related events, too much emphasis should not be given to the word REACH as this may not attract many participants;
- Users should be able to identify FAQs (i.e. it needs to be clear that such Q&As represent harmonised advice from ECHA, national helpdesks and the European Commission), but the FAQs do not necessarily need to be tagged as FAQs on ECHA's Q&A web page.
- Member States have started contacting pre-registrants, and there is a desire for ECHA to also consider this.

Annex I - List of participants

HelpNet members

Austria KRATZ Karin **Belgium** HOYAUX Daphné

GAIGUROVA Margarita Bulgaria

Croatia KAJIC Silva

ORPHANOU Maria Cyprus

Czech Republic **KOLAR Jan** Denmark DYEKJAER Sidsel

Estonia AMELKINA Anna

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France **DUFFORT Gaëlle** Germany HAAS Claus, WIANDT

Suzanne

Greece **CHATZIANTONIOU Dimitrios**

Hungary NYITRAI Viktor Péter **Ireland** RODGERS Karen **GIANNOTTI Francesca** Italy

Latvia **RUBENE** Līga Luxembourg **BIWER Arno**

KJUUS Berit Eyde, TVERMYR Norway

Marianne

Poland DOMANSKI Krzysztof Romania **CAROLE Nicoleta** Slovakia SLIMAKOVA Anna Slovenia MENARD SRPČIČ Anja

Spain ZAMORA Laura

Sweden KRAMER Helena, WESTOO

Cecilia

Netherlands van IERSEL Petrus UK

PEPPIN-HUGHES Lindsay

Observers

CEFIC JANOSI Amaya

Serbia GRUJIC Jelena, RASOVIC

Aleksandra

TIRYAKI Ilknur Ozlem Turkey

Invited experts

BRIGNON Jean-Marc **INERIS** (Agenda item 7.2.)

Ireland COSGRAVE Majella Kooperationsstelle LISSNER Lothar **Hamburg IFE** (Agenda item 7.2.)

PIPIRAITE-VALISKIENE Donata Latvia

ECHA staff

Representing the Units: A2, B2, C1, C2, C3, D2, D3