# HelpNet REACH Workshop: summary of discussions

**Time** 04 October 2016, 08:50-17:30
**Place** European Chemicals Agency
Annankatu 18, 00120 Helsinki, Finland

The Chair, Johan NOUWEN opened the REACH workshop by welcoming the representatives of the REACH national helpdesks (NHDs), observers and the European Commission. The names of the participants attending the events are listed in Annex I to this document.

The first day was dedicated to the REACH workshop and the REACH-IT hands-on training and it was attended by HelpNet correspondents or alternates, observers from industry, candidate countries and the European Commission.

The REACH workshop was held back-to-back with a two-day 'Training for trainers on the enforcement of exposure scenarios and the extended safety data sheets' provided by the Forum. The opportunity to join this training was opened exclusively to HelpNet REACH correspondents/alternates and the European Commission.

This document summarises discussions[1] during the REACH workshop and REACH-IT training. The agenda of the workshop was developed based on the feedback received from the HelpNet members and topics which ECHA identified as relevant for providing consistent and harmonised helpdesk advice and support for 2018 registrants and SMEs in particular.

The overall objective of the workshop was to inform NHDs on the latest developments of processes and activities carried out by ECHA since the last HelpNet meeting, raise awareness about the supporting information on ECHA's website and exchange information on frequently asked or difficult questions received by ECHA and the NHDs.

## 1. REACH workshop

### 1.1. Actions for the 2018 REACH registration deadline

In her role as coordinator of the REACH 2018 Roadmap, **Laura WALIN** (ECHA, Directorate of Registration) presented ECHA's recent and future plans under the REACH 2018 Roadmap, emphasising the importance of the NHDs, both in advising the future registrants and in reaching out to them.

The NHDs' support is becoming even more prominent for the 2018 REACH registration deadline, when most of the registrants are expected to be SMEs; they might feel more comfortable to communicate in their own languages with their own national helpdesk and authorities.

[1] 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.

She briefly explained the following 2018 Roadmap phases:

- **Phase 4: Assessing hazards and risks**[2], launched on 19 July 2016 and followed by a supporting package containing: new support web pages with practical advice, new/updated practical guides[3] and guidance documents, support for reduced information requirements (Annex III inventory, examples for application of the inventory), new version of Chesar, and a communication package press release translated in all EU languages, special e-News, activities in social media (LinkedIn, Twitter) and a webinar[4] delivered on 20 July 2016.

- **Phase 5: Prepare your registration as a IUCLID dossier**[5], launched on 3 October 2016, with a similar supporting package as above and a webinar scheduled on the date of the REACH workshop, 4 October 2016.

- **Phase 6:** Submit your registration, launch planned on 29 November 2016, and a webinar on 30 November. By the same date, publication of a revision of **phase 2: How to find your co-registrants** is foreseen**.**

- Activities from 2017 onwards: the Roadmap implementation will shift from content production to communication activities, focusing on outreach activities and practical examples, with virtual meetings of the REACH 2018 Communicators' Network.

- **Phase 7: Keeping the registration up to date**, planned for the second half of 2018.

**Key messages**: ECHA's REACH 2018 Roadmap is about to be completed. NHDs are invited to promote the existing material and forthcoming Roadmap phases in their networks.

- ECHA's REACH 2018 web pages: https://echa.europa.eu/reach-2018
- ECHA on LinkedIn: https://www.linkedin.com/company/454521

## 1.2. Information requirements for 2018 registration

**Laurence HOFFSTADT** (ECHA, Evaluation Unit) presented the changes to the REACH annexes with an impact on the information requirements for registrants, especially those submitting information to ECHA for the 2018 registration deadline.

In December 2015 and April 2016, amendments[6] to the REACH annexes were voted and have an impact for REACH 2018 registrants. Annex VII (1-10 tpa), Annex VIII (10-100 tpa), the adaptation options according to Annex XI and the provision to consider animal testing as a last resort are relevant for the 2018 registration deadline. It was stated that omitting the animal testing should not compromise the safe use of the substance.

Laurence HOFFSTADT presented then the summary of endpoints relevant for 2018 and the test guidelines relevant for non-animal test methods – a good reference for advising registrants. Promotion of alternatives to animal testing is one of the pillars in REACH, and ECHA is active in promoting this (e.g. update of the Guidance for acute toxicity – the annex proposes a new strategy to reduce the number of animal studies).

[2] Phase 4: https://echa.europa.eu/reach-2018/assess-hazard-and-risk.
[3] Practical guide for SME managers and REACH coordinators – 'How to fulfil information requirements for chemicals at 1-10 and 10-100 tonnes per year' and other practrical guides updated.
[4] Webinars: https://echa.europa.eu/support/training-material/webinars/2016.
[5] Phase 5: https://echa.europa.eu/reach-2018/prepare-your-registration-as-a-iuclid-dossier.
[6] Recent amendments to REACH Annexes covered: skin corrosion/irritation, serious eye damage/eye irritation, acute dermal toxicity and skin sensitisation.

ECHA has published its recommendations for using new or revised OECD test guidelines[7] related to serious eye damage/eye irritation and skin corrosion/irritation. Non-animal testing is now the default approach to gather information.

More information about the changes to the REACH annexes have been provided in a comprehensive presentation given by Laurence HOFFSTADT during a Chemical Watch webinar[8]. The links were made available for HelpNet members on S-CIRCABC, before the meeting.

ECHA also provides you with direct links to the amending regulation documents, which are available in all EU languages (if requested by registrants):

- http://eur-lex.europa.eu/eli/reg/2016/863/oj
- http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478880381154&uri=CELEX:32016R1688

The second topic presented by Laurence HOFFSTADT was on practical guides[9] recently published by ECHA to support registrants:

- The **Practical guide for SME managers and REACH coordinators** with a standard structure and simple language has been published and recently translated in all EU languages. The guide is intended for people responsible for gathering all information needed to compile a technical dossier for a substance to be registered under REACH.

- The updated **Practical guide on how to use alternatives to animal testing to fulfil your information requirements for REACH registration** provides recommendations based on ECHA's experience so far with the registration and dossier evaluation processes.

  It aims to inform registrants about their obligations to avoid unnecessary testing on vertebrate animals, yet still ensure that registrants have sufficient information on the properties of their substances for classification and risk assessment. The guide explains the increasing opportunities for using alternatives to animal testing and how to report these correctly.

- The updated **Practical guide on how to use and report (Q)SARs** provides an overview of important aspects to consider when predicting properties of substances using (Q)SAR models. The guide gives general information about how to use (Q)SARs, examples of good practices and freely available software programs.

**Key messages**: The amended REACH annexes[10] are making non-animal testing the default requirement. ECHA and NHDs have to remind registrants to consider, whenever possible, the use of alternative methods[11].

[7] Advice on skin and eye irritation testing helps to reduce animal tests: https://echa.europa.eu/view-article/-/journal_content/title/advice-on-skin-and-eye-irritation-testing-helps-reduce-animal-tests
[8] Chemical Watch webinar on **Alternatives to animal testing**: Video and slides
[9] Practical guides: https://echa.europa.eu/practical-guides
[10] REACH annexes amended: https://echa.europa.eu/view-article/-/journal_content/title/reach-annexes-amended-registrants-to-use-alternative-test-methods
[11] Registrants to use alternative test methods for skin sensitisation: https://echa.europa.eu/view-article/-/journal_content/title/registrants-to-use-alternative-test-methods-for-skin-sensitisation

Aiming to better support SMEs, ECHA created or updated some practical guides. NHDs are invited to promote the documents in their networks. Since ECHA has withdrawn some practical guides from its web pages, as their content has been integrated in the updated ones, NHDs should consider revising the links used as a reference to the previous practical guides.

## Questions and answers session

- *What is the time undertaken by ECHA to finalise the completeness check for a registration dossier submitted after the 2018 registration deadline*

The time undertaken by ECHA to finalise the completeness check is three weeks for registrations of phase-in substances submitted after the registration deadline of 31 May 2018. It is, exceptionally, three months if the registration dossier is submitted in the course of the two-month period preceding the registration deadline (Article 20 of REACH).

- *Are the amendments to Annexes VII and VIII published on ECHA's website? What about information requirements?*

Amendments to Annexes VII and VIII to REACH are not published on ECHA's website, but on the European Commission's[12] website, and the links have been provided in the presentation **Information requirements for 2018 registration** and in the footnote.

For information required for a standard registration[13] of 1-10 tonnes a year (Annex VII to REACH) and 10-100 tonnes a year (Annex VIII to REACH), information is available on ECHA's website (see links provided in the footnote).

- *How much time does a company need to finalise a registration dossier? Can a timeline be provided by ECHA as orientation?*

ECHA has considered illustrating the timelines, but, after discussing this within the REACH 2018 Communicators' Network, this approach seemed not to be the best solution. Instead, ECHA is considering providing case examples in the future.

Regarding the urgency contained in ECHA's messages, this is based on the feedback received from companies on the indicative time needed between booking a service provider, sign a contract, having the tests conducted and receiving the test reports.

- *Is the list of substances with lead registrants published on ECHA's website and how often will ECHA update the list?*

Indeed, ECHA has published a list[14] of about 7 000 substances that have an active lead registrant. It includes the names of those lead registrant companies who have given their permission to have their names published.

The list is available in PDF and Excel formats - under the 2018 Roadmap (main page) and phase 2 page. Currently, the list is updated manually, on a monthly basis. The ultimate aim is to have the data automatically retrieved from the REACH-IT database.

[12] Annexes VII and VIII to REACH - amendments:
https://members.wto.org/crnattachments/2015/TBT/EEC/15_3846_00_e.pdf
https://members.wto.org/crnattachments/2015/TBT/EEC/15_3846_01_e.pdf
[13] Information requirements according with Annex VII and VIII to REACH:
http://echa.europa.eu/regulations/reach/registration/information-requirements
[14] List of substances with lead registrants: https://echa.europa.eu/view-article/-/journal_content/title/list-of-substances-with-lead-registrants-available

Laura WALIN explained then the logic behind the REACH 2018 information available on ECHA's website. A user will always find information regarding:

- Regulations in ECHA's remit under: **ECHA › Regulations › REACH**[15]
- Practical advice on specific areas, e.g. REACH processes, guidance documents, testing methods, SMEs, etc. under **ECHA › Support**[16] web pages.

- *Does ECHA provide any estimates of test costs (e.g. of non-animal testing?)*

Such estimates are provided on ECHA's web pages (phase 4)[17]. The information on the indicative costs for generating new information comes from a report published by the Commission in 2015, referring to a CEFIC testing catalogue of 2012. However, it mainly refers to *in vivo* data. The information is published to give companies an illustration of the order of magnitude of the costs back in 2012. The costs, however, should not be used as the bases for data-sharing negotiations or disputes.

- *Could ECHA explain the provisions of Annex III to REACH?*

Comprehensive information on the Annex III criteria is available on ECHA's website[18]. ECHA compiled an inventory of substances[19] likely to meet the criteria of Annex III of REACH and examples for application of the Annex III criteria[20]. The relation between the Annex III and the fee waiver will soon be published as a Q&A on ECHA's website and the Member States will be informed accordingly.

- *Will ECHA publish information on Brexit?*

The HelpNet Secretariat provided participants with a room document on the Brexit and explained that this document reflected ECHA's current point of view. It contains replies to enquiries provided by ECHA and the UK helpdesk to their customers. It was clarified that Andreas HERDINA is following Brexit on behalf of the Agency. In ECHA's understanding, nothing will change until the British Government has invoked Article 50 of the Treaty of the European Union (EU). Therefore, at this moment in time, there is no need for potentially affected EU companies to assume any need for changes in complying with their REACH, CLP, BPR or PIC-related obligations.

## 1.3. Substance identification profile (SIP)

**Bernadette QUINN** (ECHA, Substance ID and Data Sharing Unit) presented an overview of the substance identification profile (SIP), current status of its implementation in IUCLID 6 and the ongoing guidance updates.

The SIP terminology was developed by CEFIC, before the 2010 REACH registration deadline, aiming to help pre-SIEFs and SIEFs document the identity profile for their joint registration.
The SIP covers the name, other identifiers and the compositional profile of a substance to be

[15] Regulations web pages: https://echa.europa.eu/regulations/reach/
[16] Support web pages: https://echa.europa.eu/support.
[17] Indicative costs for generating new information: https://echa.europa.eu/support/registration/strategy-for-gathering-your-data/practical-considerations-before-testing.
[18] Reduced information requirements: https://echa.europa.eu/support/registration/what-information-you-need/reduced-information-requirements.
[19] Annex III inventory: https://echa.europa.eu/information-on-chemicals/annex-iii-inventory.
[20] Examples for application of the Annex III inventory: https://echa.europa.eu/documents/10162/22332820/annex_iii_examples_en.pdf/816fb5ff-af52-45ec-a7e0-5f5d0ff3ca77.

registered jointly. According to Article 11 of REACH and the Implementing Regulation on joint submission and data sharing, all parties intending to register the same substance identity need to come together and submit one registration (OSOR principle).

To illustrate how the SIP is an integral part of the joint submission, Bernadette QUINN presented eight steps that potential registrants would need to undergo from pre- to post-registration, before receiving a registration number and having the information in the registration dossier disseminated on ECHA's website:

1. Determining the registration obligations
2. Using the Guidance on SID to define the substance ID
3. Defining the SIP for registration
4. Agreeing on the SIP for registration
5. Data gathering/generation stage
6. Reporting the data in IUCLID format
7. Submission of the dossiers through REACH-IT
8. Dissemination of the registration dossiers in ECHA's database

With the release of IUCLID 6, reporting composition records (so-called boundary composition records) for the SIP is a mandatory business rule for the lead registrant of a joint submission. Illustrative examples were provided on legal entity compositional information and boundary compositions covering the compositional profiles reported in the lead registrant dossier. The benefits of having the SIP reported in the IUCLID format were explained.

Updates[21] of guidance documents are ongoing and the anticipated dates of publication range between the end of 2016 and beginning of 2017. These will provide advice to potential and existing registrants updating their registration dossiers – i.e. Appendix 3 of the 'Guidance on Identification and naming of substances under REACH and CLP', 'Guidance on registration', 'Guidance on data sharing', Appendix on 'Guidance on recommendations for nanomaterials'.

**Key messages:** The substance identification profile (SIP) provides the boundaries of the substance identity for the joint registration. The new fields in IUCLID facilitate bridging of what is covered with what is reported in the registration dossier. ECHA is collecting information on the experience related to the use of the existing guidance and the potential needs to develop further guidance on this matter.

## Questions & answers session

- *If new registrants joining a SIEF are broadening the scope of an existing registered substance, can or should the SIP be updated in the registration dossier?*

In principle, if the new registrant is broadening the scope of the registered substance, the registration indeed has to be updated following the agreement within the SIEF. The SIP is not going to block any new registrants joining a joint submission.

- *Will there be any examples of SIP for well defined and UVCB[22] substances in the updated SID[23] guidance?*

[21] Ongoing guidance consultation: https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach
[22] UVCB - Unknown or variable composition, complex reaction products or biological materials
[23] The version before proposed amendments of the SID guidance (Guidance for identification and naming of substances under REACH and CLP) and the new appendix are available on the ECHA website, at:

The new Appendix 3 to the SID guidance describes the principles of defining a SIP for well-defined and UVCB substances, based on the principles described in the main guidance document.

## 1.4. Authorisation

**Thierry NICOT** (ECHA, Risk Management Implementation Unit) presented the state of play of the applications for authorisation (AfAs), including: statistics on received applications; number of RAC/SEAC opinions and decisions issued by the Commission; update on Q&As; legal entity changes; downstream user notifications (Article 66 of REACH); IT tools and guidance for the submission of AfAs.

**Brief state of play**: ECHA has received 91 AfAs for 155 uses so far. RAC and SEAC have delivered 157 opinions, and the Commission has issued 59 decisions (as of 03 October 2016[24]). The AfAs received and evaluated cover uses of Cr(VI) substances, TCE[25], EDC[26], diglyme[27], arsenic acid, technical MDA[28], lead chromate, and lead chromate pigments.

The Commission has decided on uses of DEHP[29], DBP[30], diarsenic trioxide, HBCDD[31], TCE, and lead chromate pigments. It is expected that the peak with Cr(VI) AfAs, that ECHA is currently dealing with, will translate to the Commission next year.

**Update of Annex XIV**: The update of Annex XIV has been postponed for a while. ECHA is still dealing with the submitted AfAs, but there are no new dossiers expected until the Annex XIV is repopulated with new SVHCs. The next amendment is expected to take place in early 2017.

**AfA Practical guide:** The Commission has asked ECHA to prepare a practical guide to instruct industry how to prepare fit-for-purpose AfAs. For this reason, the **AfA task force**[32] has been set up and its objective is to deliver this practical guide by the end of 2016.

**Review reports:** A misperception seems to exist within industry (in particular with SMEs and Cr(VI) applicants) that once the review period (e.g. four, seven or 12 years) of a granted authorisation is over, companies that have not succeeded in substituting by that time will have to shut down their business or relocate, without being able to extend the authorisation period.

ECHA would like to clarify that a granted authorisation may be requested to be extended by submission of a review report[33] no later than 18 months before the end of the review period. The review report will be evaluated by RAC and SEAC, and finally by the Commission. In some cases, the circumstances of the authorised use may have changed, or new information on

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https://echa.europa.eu/guidance-documents/guidance-on-reach
[24] Statistics on received applications: https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications
[25] TCE - Trichloroethylene
[26] EDC - 1,2-dichloroethane
[27] Diglyme - Bis(2-methoxyethyl) ether
[28] Technical MDA - Formaldehyde, oligomeric reaction products with aniline
[29] DEHP - Bis(2-ethylhexyl) phthalate
[30] DBP - Dibutyl phthalate
[31] HBCDD - Hexabromocyclododecane
[32] Task Force on the workability of AfA: https://echa.europa.eu/documents/10162/13637/afa_task-force_report_en.pdf
[33] Review report of an authorisation: https://echa.europa.eu/documents/10162/13637/authorisation_review_report_en.pdf/cbc94819-bdb8-4d98-8687-7372df779bcf

alternatives may have become available. In any case, it is important that the NHDs convey this message to industry so that companies become aware that they have this possibility as well.

The first review reports on the use of DEHP are expected in mid-2017. ECHA is currently setting up a process to assess these types of dossiers.

**Updates on Q&As**: At the moment, ECHA's support web pages contain 92 Q&As on authorisation[34]. Recently Q&A updates include: clarifications on scientific research and development (SRD) exemptions issues (e.g. monitoring/quality control, sampling, and steps preceding SRD end-use), OR's role as an AfA applicant, and status of ammunition cartridges as articles.

**Legal entity changes**: While the legal entity change process is common in registration, it is a new process in the context of AfAs. Several questions have been received by ECHA, which triggered a set of Q&As clarifying various aspects of the newly established process: types of change (e.g. name, OR, ownership), stages of change (e.g. submission/opinion/decision stage), IT tools, templates, analysis of impacts, timelines. The Q&As will be published soon.

**IT tools**: The releases of REACH-IT and IUCLID 6 in May 2016 did not bring any significant changes to the AfA submission process. ECHA's manual **How to prepare an application for authorisation**[35] has been published, replacing the Data Submission Manual - Part 22.

Main changes include the following:

- The pre-configured IUCLID 5 for AfA is not relevant anymore
- A validation assistant has been implemented for AfAs for certain business rules checks
- The instructions for AfAs in Sections 3.5 and 3.10 have been slightly updated
- The OR information has to be filled in Section 1.7 of IUCLID

**Downstream users (DUs) notifications**: Based on an authorisation granted to an applicant up their supply chain (Article 56(2) of REACH), DUs using a substance that is in Annex XIV of REACH have to notify[36] (free of charge) their use[37] to ECHA (Article 66(1) of REACH). DUs need to fulfil this legal requirement within three months after the first supply of the substance, following publication of the Commission's decision in the Official Journal. They also need to comply with the conditions stated in the authorisation decision and pass relevant information to their customers.

There is a webform[38] available for submitting such notifications (accessible through REACH-IT or in ECHA's Article 66 DU notification web page[34]). The DU can select their authorised use from the list and may, if they wish, submit additional information (e.g. quantity used, number of workers exposed). ECHA has already started receiving the first DU notifications on authorised uses. It is important that the NHDs raise awareness regarding this legal requirement.

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[34] Q&As on authorisation:
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Authorisation
[35] How to prepare an AfA:
https://echa.europa.eu/documents/10162/22308542/manual_afa_en.pdf
[36] Submitting downstream user notification of authorised uses:
https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use
[37] DU notification for use of an authorised substance:
https://newsletter.echa.europa.eu/home/-/newsletter/entry/4_15_downstream-users-notify-echa-if-you-use-an-authorised-substance
[38] Webform: https://idp-industry.echa.europa.eu/idp/

Recently, ECHA has been receiving several questions on AfAs, in particular regarding confusion between the Candidate List/Authorisation List obligations, exemptions from the authorisation requirement, supply chain mechanisms, current status of opinions and decisions on AfAs. Most of these questions have been tackled using the existing Q&As on authorisation on ECHA's website.

**Key messages**: NHDs could help by raising awareness in their networks regarding the possibility of submitting review reports to request extension of the authorisation period, and the obligation for DUs relying on a granted authorisation up their supply chain to notify their uses to ECHA (Article 66(1) of REACH).

ECHA would appreciate hearing about the numbers of AfA-related questions received by the NHDs, the frequently asked questions, and the ones that they find difficult to respond to. In addition, ECHA is inviting the NHDs to provide feedback on the accessibility and clarity of AfA information available on ECHA's web pages. Any suggestions are welcome in the coming weeks.

## Questions & answers session

- *Are there any updates on the low volume exemptions or AfAs for legacy spare parts?*

ECHA has prepared draft instructions and templates for the submission of simplified AfA dossiers for low volumes of Annex XIV substances. The issue is currently pending with the Commission, due to legal considerations on whether to proceed by an update of Annex I to REACH or an Implementing Act.

- *Some SME companies (e.g. in Germany) have expressed that they are experiencing language difficulties within the AfA process. Is ECHA planning to publish anything on this matter?*

ECHA has published two Q&As[39] clarifying that AfAs can be submitted in any of the official EU languages selected by the applicant. However, the entire AfA, including attachments, must be submitted in the same language.

Nevertheless, ECHA's experience so far has shown that it is tremendously difficult to deal with AfAs submitted in languages other than English, since all documents at each step of the process need to be translated. This is costly and time-consuming and affects the overall timing of the opinion and decision-making process. In principle, RAC and SEAC have 10 months to issue their opinions and the Commission has six months to adopt its decision[40] on an AfA. When an AfA is submitted in a different language, this could translate in a multiplication of the timelines by a factor of 2 or 3.

- *If a company has applied for authorisation and is waiting for the Commission's decision on an AfA, can it continue storing the Annex XIV substance?*

The Commission clarified that a Q&A covering this issue was finalised and will be published soon under the Authorisation section of ECHA's Q&A support web pages.

[39] See Q&As webpage: Q&A 129 and Q&A 588
[40] See: Q&A 584

## 1.5. Restrictions

**Kirsi SIHVONEN** (ECHA, Risk Management Implementation Unit) presented the latest developments under the restriction process[41] since the last REACH workshop. She introduced the current restriction proposals; Annex XVII entries, including development of new Q &As; update of guidelines; and table of restrictions available on ECHA's website.

She briefly referred to the substances for which an opinion was provided by ECHA's scientific committees - RAC[42] and SEAC[43] - and submitted to the European Commission:

- 1-Methyl-2-pyrrolidone (NMP)
- Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE) (note: voted in favour at the REACH Committee)
- Bisphenol A (4,4'-isopropylidenediphenol) (note: voted in favour at the REACH Committee)
- Methanol
- Octamethylcyclotetrasiloxane (D4)
- Decamethylcyclopentasiloxane (D5)
- Perfluorooctanoic acid (PFOA) including its salts, and any other substance having linear or branched perfluoroheptyl derivatives

For these substances, the Commission will prepare a draft amendment and - if not opposed by the European Parliament - adopt the restriction decisions and publish them in the Official Journal as an amendment to Annex XVII to the REACH Regulation. Then, as a consequence, NHDs might expect to receive enquiries from manufacturers, importers, distributors, downstream users or retailers.

Current restriction proposals under opinion development[44]:

- TDFA (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (perfluorinated silanes) for use in consumer spray products
- Phthalates used in articles
- DMF (N,N-dimethylformamide) for industrial and professional uses (not in the conformity and thus for the Member State to decide if the dossier will be resubmitted)

Future opinion making on restriction intentions[45]:

- Isocyanates for industrial and professional uses (submission 10/2016)
- Lead stabilisers used in PVC (submission late 2016)
- Lead in shot used in wetlands (submission mid 2017)
- CMRs and sensitisers used in tattoo inks & permanent make-up (submission in 2017)

According to Article 69(2) of REACH, ECHA is investigating if the use of the following substances listed in the Authorisation List (Annex XIV), are posing a risk to human health or the environment:

[41] Restriction process:
https://echa.europa.eu/regulations/reach/restrictions/restriction-procedure/restrictions-process
[42] RAC - Committee for Risk Assessment.
[43] SEAC - Committee for Socio-economic Analysis.
[44] Submitted restrictions under consideration:
https://echa.europa.eu/restrictions-under-consideration
[45] Restrictions intentions:
https://echa.europa.eu/registry-of-current-restriction-proposal-intentions

- Phthalates (restriction proposal prepared, submitted to ECHA and under consideration by RAC and SEAC)
- Musk xylene, MDA[46], HBCDD[47], arsenic trioxide (not proposing any restrictions)
- Lead chromates, TCEP[48], TCE[49], etc. (reports under consideration).

Preliminary investigations due to requests from the Commission to assess if the substances could pose a risk:

- Lead shot (other ammunition) in non-wetlands/fishing weights
- Formaldehyde and formaldehyde releasers
- Rubber crumb used in artificial playing surfaces
- Cadmium and its compounds in recycled plastics
- BPS (bisphenol S) in thermal paper, used as a substitute of BPA (bisphenol A)
- Cobalt and possibly restriction review obligations for: PAH (entry 50) and lead in jewellery and in consumer articles (entry 63)

In addition, the European Commission asked ECHA to compile a list of CMR substances that could potentially be present in textile and clothing articles. The information should be gathered from various sources, including the REACH registration data.

Regarding questions and answers on restrictions[50], ECHA has used the input received from NHDs and published on its website Q&As covering the areas: narrative descriptors/generic terms; definition of articles and scope. The next batch of Q&As is under preparation and would include examples on: REACH restrictions in textile and leather articles, paints, electronic devices; scientific research and development; information on restrictions added in SDS (part 15); and several questions submitted by Forum and HelpNet members.

Concerning guidelines, Kirsi SIHVONEN informed that the guideline on lead and its compounds in consumer articles that can be placed in the mouth by children (entry 63, par 7-10) has been published in May 2016 as a Q&A. Two other guidelines – on nickel in articles intended to come in 'direct and prolonged contact with the skin' (entry 23) and on polycyclic aromatic hydrocarbons (PAHs) in consumer articles (entry 50) – have been drafted and are waiting for comments from the Commission.

A call for comments and evidence is expected to start soon, giving interested parties a chance to submit information. Then, the updated guidelines will be submitted to CARACAL seeking to reach an agreement before publication.

Kirsi SIHVONEN then presented the table of restrictions[51] and ECHA's plan to visualise the guidelines and the Q&As in a better way on ECHA's website.

**Key messages:** ECHA would appreciate receiving NHDs' feedback on the restrictions pages on ECHA's website, especially on the Annex XVII table. Any suggestions for further improvement[52] are welcome by the end of November.

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[46] MDA: Formaldehyde, oligomeric reaction products with aniline
[47] HBCDD: Hexabromocyclododecane
[48] TCEP: tris(2-chloroethyl)phosphate
[49] TCE: trichloroethylene
[50] Q&As on ECHA's website:
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/restrictions
[51] Table of substances restricted under REACH:
https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach
[52] Please send your feedback to ECHA by using the email address:
restriction@echa.europa.eu

## Questions and answers session

- *Companies searching for restriction information on ECHA website (Annex XVII) would rather search by product type and not by substance name.*

The current search by substance name in the table relates to the dissemination site. A new feature of the searching function added to this table might take some time, however it will be communicated in-house and further investigated.

- *One inconvenience - for companies and the general public - is that the table and the introductory text are only in English. Is ECHA planning to translate this?*

The restriction decisions are translated in all EU languages. As for the translation of the table and the introductory text, this will be discussed internally.

- *When will information for standards on PAHs in extender oils be updated?*

If needed, ECHA will check and update the information on its website. In addition, the Commission initiated a project on the migration of polycyclic aromatic hydrocarbons (PAHs) in consumer articles aiming for the possible development of a European standard.

The FORUM's compendium on analytical methods[53] will be updated in 2018.

**Key messages**: ECHA invites NHDs to express their views on the outcome of the Annex XVII project, restriction entries and the supporting information available on ECHA's website.

## 1.6. REACH 2018 - Prepare your registration as a IUCLID dossier[54]

In April 2016, REACH HelpNet members received a training on the main changes in IUCLID 6 and an overview of the supporting material to be made available with the release of IUCLID 6 (i.e. embedded help system in the application, new streamlined and simplified user manuals available on the ECHA website, short video tutorials). The webinar delivered on 1 June 2016 covered the transition from IUCLID 5 to IUCLID 6 (for advanced users).

The webinar of 4 October, focused on practical steps that are needed to successfully create a complete registration dossier in IUCLID. It is targeted to registrants who are registering a substance for the first time and want to use IUCLID to create a registration dossier.

The webinar covered topics ranging from the installation of the IUCLID 6 application to the creation of a IUCLID 6 registration dossier, including the verification that all required information has been filled-in, using the embedded validation assistant. It also explained how, under certain conditions, a registration dossier for a member of a joint submission can be created online.

On the LinkedIn showcase page, how to create a registration dossier either with IUCLID or directly in REACH-IT is described: https://www.linkedin.com/company/reach-2018.

[53] Forum compendium on analytical methods (versions 1.0 and 2.0):
https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf
https://echa.europa.eu/documents/10162/13577/methodology_analytical_methods_en.pdf
[54] Webinars:
https://echa.europa.eu/support/training-material/webinars/2016

## 1.7. Commission's Implementing Regulation (EU) 2016/9 on joint submission of data and data sharing

The Chair introduced the next topic on the agenda, the Implementing Regulation on joint submission of data and data-sharing (IR)[55] and the experience gathered by ECHA and industry since January 2016, the date of entering into operation of the new regulation.

### 1.7.1. SIEF formation and data-sharing negotiation – ECHA's perspective

**Maia SOKOLOVA** (ECHA, Substance Identification and Data Sharing unit) presented ECHA's perspective and experience on **SIEF formation[56] and data sharing negotiations[57]**.
The presentation focused on the implementation of REACH principles of data sharing (DS), ECHA's activities regarding DS disputes[58] and the revision of guidance documents[59] reflecting the new elements brought by the new regulation.

The Implementing Regulation (IR) strengthens the enforcement of the OSOR principle, and brings more clarity on the obligations of DS and cost sharing. It also expands the scope of the data-sharing disputes by allowing an access (token) to be provided to the joint submission (JS), where one of the JS members is opting-out and they could not reach an agreement on access to the JS. New requirements which aim at fostering transparency are:

- Itemisation (breakdown) of costs (related to both data generation and administrative activities) in DS agreements; linking cost items with data requirements and providing a justification for each cost item, considering potentially past, present and future cost gererating factors;

- A cost-sharing model which may include a reimbursement mechanism, facilitating DS negotiations between new registrants and existing registrants, reinforcing equal rights for all co-registrants.
-

Back in 2013, during the REACH SME workshop[60] organised by the Commission and ECHA and through a survey conducted by ECHA, SMEs showed their concern that cost-sharing methods are unclear and difficult to challenge, that administrative costs are not proportionally shared between co-registrants and, often, that potential registrants have to pay for data they do not need (flat rate letter of access (LoA)).

On the other hand, existing registrants' opinions were that SMEs criticise large companies for the high costs of REACH implementation; that potential registrants have been given

[55] Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 (REACH): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN
[56] Practical advice for new SIEFs: https://echa.europa.eu/support/registration/working-together/practical-advice-for-new-siefs.
[57] Practical advice for data-sharing negotiations: http://echa.europa.eu/regulations/reach/registration/data-sharing/practical-advice-for-data-sharing-negotiations
and Typical cost elements in data-sharing negotiations: http://echa.europa.eu/documents/10162/13631/factsheet_costs_datasharing_en.pdf.
[58] Data-sharing disputes in practice: https://echa.europa.eu/support/registration/working-together/data-sharing-disputes/data-sharing-disputes-in-practice
[59] Guidance on REACH: https://echa.europa.eu/guidance-documents/guidance-on-reach
[60] REACH SME workshop in 2013: http://www.euconf.eu/reach2013/en/registration/index.html

disproportionate power to challenge the existing agreements, and that the new regulation may even further increase the administrative cost.

From ECHA's perspective, data were successfully shared in more than 6 000 joint submissions showing that SIEFs are generally working well. So far, less than 1% have been escalated to ECHA as data-sharing disputes.

The first dispute submitted to ECHA, after entering into force of the IR, concerned the lack of transparency regarding cost breakdown and unjustified price increase of LoAs. Information about this case and non-confidential versions of ECHA's decisions on disputes are published online[61]. The second DS complaint escalated to ECHA refers to access to the joint submission (JS) and the assessment of the case is ongoing.

With the expected increases in registrations before the 2018 deadline, ECHA estimates an increase for the disputes for the period 2017-2018 (from 80 to 170).

The guidance on data sharing is currently under revision, and consultation[62] with the CARACAL is taking place in late October. The new version of the guidance document will include the reference to the IR; new practices under the IR; key issues in data-sharing agreements, in particular itemisation and distinction between study and administrative costs; disputes, etc. Depending on the complexity of the comments received during the last step of the consultation process, the updated guidance on data-sharing may be ready by the end of the year

**Key messages**: The IR was introduced to clarify and reinforce data-sharing principles as well as to consolidate them with the JS obligation. On the other hand, it emphasises the concept that sharing of data should not be for profit. IR may require industry to revaluate data sharing and JS practices and take corrective actions when needed. However, IR is not supposed to or should not have major impacts on a well established and properly functioning SIEF.

Andreas Herdina, ECHA's SMEs Ambassador, is taking a closer look at some practices[63] registrants have for sharing data and its costs. He strongly encourages companies to ensure that their contractual conditions respect the principles of REACH and IR of fair, transparent and non-discriminatory cost sharing.

### 1.7.2. SIEF formation and data-sharing negotiation – industry's perspective (German NHD presentation)

Based on the feedback received by the German NHD from registrants and SMEs, Suzanne WIANDT presented the NHD perspective on the implementation regulation (IR) on REACH principles of data sharing.

Principally, the IR is found extremely necessary, as it provides legal certainty on the OSOR principle and increases transparency. However, from the feedback received by the DE NHD, increased transparency in negotiations can induce higher costs in some cases. Still, NHDs cannot decide whether data and cost sharing is fair or non-discriminatory or provide advice to companies on this matter.

[61] ECHA decisions on data sharing disputes under REACH: https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach
[62] Ongoing guidance consultation: https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach
[63] ECHA weekly news, Keeping an eye on data-sharing principles: https://echa.europa.eu/view-article/-/journal_content/title/echa-weekly-31-august-2016.

For a member registrant (MR), using their own data for their registrations or paying only for the data needed is still difficult and often the existing registrants do not allow MRs to opt-out of some or all of the joint data. LRs sometimes ask for exorbitant high prices for the LoAs, thus preventing access for their competitors on the market. In one case reported to the German NHD, the Implementing Regulation provisions regarding transparency were used as a justification to increase the cost of the LoA by 30%. In reverse, MRs expect that the cost breakdown is free of charge and sometimes quote the practical advice published on ECHA's[64] website.

From a NHD perspective, cost itemisation - as part of the administrative cost - should be shared between all registrants and provided free of charge to new potential registrants on request.

For LRs, in many cases, it is however difficult to get reliable commitments from new registrants to buy a LoA. LRs would prefer to have the MRs sign a non-disclosure clause (as part of the SIEF agreement) before providing them the cost itemisation. Thus, acknowledging the effort to perform such detailed cost itemisation, the German NHD is of the opinion that it could be justified that at least a non-disclosure agreement is signed by potential MRs. Especially as in some cases, it was reported to the German NHD that MRs apparently require unnecessary/excessive itemisation, disproportionate with the effort and outcome of the data-sharing (DS) agreement.

**Key messages:** NHDs are welcoming the reinforcement of the OSOR principle and transparency as stipulated in the IR. Co-registrants must make every effort to reach a DS agreement. If they fail in doing so, they can submit a DS dispute to ECHA. Although NHDs cannot decide on fairness and non-discriminatory aspects of DS, they can support companies on test requirements, SID, technical issues, and have a say on transparency.

### 1.7.3. SIEF formation and data-sharing negotiation – industry's perspective (CEFIC intervention)

Amaya JÁNOSI from CEFIC presented industry's views on data sharing in the context of the new IR, and ECHA's guidance on DS. She also presented the supporting activities targeted to companies preparing for the 2018 registration deadline (e.g. updating agreement templates).

Industry welcomed the IR adopted by the European Commission allowing a good functioning of DS agreements by reinforcing the provisions on DS and the JS of REACH. In industry's opinion, the IR contains, on one hand, some generic obligations (very broad) with strong requirements and on the other hand, some specific and precise obligations making the adoption less practical.

Some particular concerns have been expressed on some workability requirements as retroactive applicability of the act; unanimity of provisions, and the power given to any new potential registrants joining an existing SIEF.

In practice, any potential registrant may ask the LR to consider specific adaptations of the itemisation of costs and challenge the DS and cost model. If only one member disagrees with the DS agreement or the itemisation model, this would affect the conclusiveness of the SIEF/consortium agreement or LoA and obstruct the JS to proceed with the registration.

[64] Practical advice for data sharing negotiations: https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations

Industry considers that such discussions and the decision-making process might not be always practical, pragmatic and workable.

Regarding the guidance on DS, industry is expecting a clear and a comprehensive guidance. The new version should support companies to put into practice the IR, and ensure that companies do not benefit from an unfair cost advantage. Industry would expect further advice on requirements as: how to achieve unanimous consensus, or make every effort to reach an agreement on sharing of information.

Industry is expecting that issues such as: getting a LoA, long delay responses from the LR; new registrants getting upfront a clear breakdown of costs; contract and data set of information not ready in time - will be solved by the implementation of the new IR. Also, industry's perception is that the adoption of the IR may trigger more DS disputes in the coming years, consuming resources of all parties.

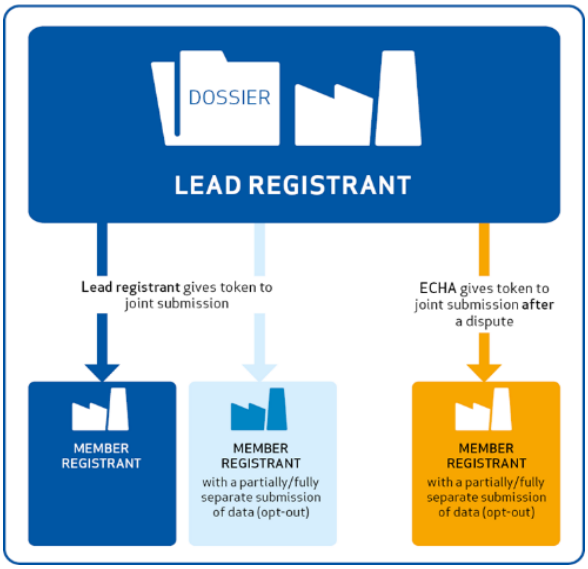
In view of the 2018 registration deadline, industry anticipates that many of the new registrants who are less familiar with the REACH complexity and dynamics will disagree on the basis of costs only, deemed to be high even if they are justified, fair, non-discriminatory and transparent. Regarding requirements which remain broad and vague in the IR, the BoA may have a role to play in the future in providing additional advice and legal certainty.

Once the guidance on DS is published by ECHA, CEFIC will update the template agreements - i.e. cooperation/SIEF/consortium agreement - to include the provisions of the IR and the itemisation of costs and data. This will give companies, particularly SMEs, time to prepare for the 2018 REACH registration deadline.

## Questions and answers session

- *The access to the JS with the token provided by ECHA under the dispute procedure is still unclear. Will the MR who paid for a LoA covering only the low tonnage band requirements have access to the whole registration dossier?*

All companies registering the same substance need to agree on the data for their joint REACH registration. This is a collective responsibility which applies equally to all co-registrants. In practice, companies may agree to submit information jointly with all their co-registrants, or to submit some or all information separately if they do not agree with the information submitted jointly. The figure below shows the different possible constellations within a JS:



**Member registrants (MRs)**

In most cases, registrants agree on the content of the registration dossier and the joint data is then submitted by the lead registrant on behalf of all co-registrants. The lead registrant gives the members access to the joint submission with a token in REACH-IT.

**Member registrants with a partially or fully separate submission of data (opt-out)**

Registrants can submit some or all of the data separately, if they do not agree with the selection of joint data, if the joint data is too expensive for them and they have alternative affordable data, or if submitting jointly would lead to the disclosure of confidential business information (this is called an 'opt-out').

In this case, the LR gives access to the JS with a token in REACH-IT, but the member submits their own information for the endpoints they have opted out from (see Chapter 6.4 of the *Guidance on Data Sharing* for more information).

Regardless of whether the contractual DS agreement between the potential and the existing registrant covers no, some or all data, the token issued by the LR technically enables the potential registrant to rely on all jointly submitted data – it is indeed in the responsibility/at the 'discretion' of the opting-out MR to indicate such an opt-out in the member IUCLID dossier.

Therefore, the registrants need to clarify precisely the scope of the data that is shared and preferably also to define ways of scrutinising of how this agreement is respected in their agreement. A targeted compliance check (TCC) may be launched if there are data quality issues between co-registrants.

**Member registrant with an opt-out after a 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 assesses the case, and may give permission to refer to some or all data and a token to access the joint submission. The registrant can then register in the JS with the other registrants of the same substance, relying on some or all of the joint data. In practice, ECHA provides copies of the robust study summaries as a document. The potential registrant then needs to assess if the received data is relevant, reliable and adequate, and enter it in their own dossier. When submitting it to ECHA, they will need to pass the full TCC, etc.

If a potential registrant intends to opt out, but cannot register because the LR does not give them **access to the JS**, they can also file a dispute with ECHA as a last resort.

ECHA assesses the case and may give a token to access the JS. The potential registrant can then register in the JS with the other registrants of the same substance, relying entirely on their own data. However, this token does not allow the claimant to rely on any of the data submitted in the joint dossier. The potential registrant therefore needs to complete their dossier with their own data and/or the data provided by ECHA within the scope of the dispute. The token provided by ECHA is therefore technically a 'full opt-out' token and the registrant must pass a full TCC.

As a general remark, ECHA cannot participate in any discussions between (potential) registrants. Generic advice is available in the guidance on data sharing and on the ECHA homepage. It is not in ECHA's remit to regulate or to assess the cost of shared data, as REACH gives the competence to establish the sharing of the costs following a DS dispute to national courts.

## 1.8. HelpEx unsolved and timed-out questions

Pedro ROSELLO VILARROIG introduced the three closed/unsolved questions proposed for this agenda item:

**HELPEX 12293** (authorisation process):

*'What are the options for a company (i.e., a downstream user) that has remaining stocks of a substance after the sunset date?'*

- Question was posted by UK
- Status was 'unsolved'
- Question is currently under informal consultation with the Commission

**HELPEX 13317** (registration process):

*'My registration dossier covers a low tonnage and my substance is not hazardous. Am I entitled to a fee waiver (Articles 12(1)(a) and 74)? Do I have to take into account the tonnages of the other members of the joint submission?'*

- Question was posted by ECHA
- Status was 'closed'
- Question was presented under agenda point **1.2 Information requirements for 2018 registration**. A Q&A will be published by ECHA in the coming weeks

**HELPEX 12981[65]:**

*'Does limestone which is surface treated with stearic acid (1%) have to be registered?'*

- Question was posted by Germany
- Question was presented during REACH workshop in April 2016 (action point: follow-up)
- Status was 're-opened'
- ECHA posted feedback following legal consultation

## Questions and answers session

Upon request by Suzanne WIANDT (DE), Christina LOUKOU (ECHA, Support, Forum & HelpNet Secretariat Unit) provided a brief presentation on the background of **HELPEX 12981** and Cyril JACQUET (ECHA, Legal Unit) clarified further the reasoning behind the revised legal approach.

It was explained, that, on one hand, Q&A 38 is not addressing the registration obligations of a surface-treated substance but how to convey information on surface treatment as a use of a substance. Therefore, the conditions stated in this Q&A cannot be applied to determine whether or not a surface-treated substance is subject to registration obligations.

On the other hand, considering Annex V to REACH, "registration is deemed inappropriate or unnecessary" for the basis substance (limestone) if not chemically modified, as well as for the surface-treating agent (stearic acid) and the substance formed as a result of the surface treatment (calcium stearate) if isolated from natural sources.

The principle of proportionality requires ECHA to not go beyond what is necessary to achieve the objectives pursued by the REACH Regulation (Recital 1 of REACH). Taking this into account, there will be a need for registration of the surface treated substance, if it is

[65] Following the HelpNet REACH workshop, the HelpEx Q&A 12981 was closed by Germany with the final answer: 'Registration is deemed inappropriate or unnecessary for the surface treated substance as well as the treating agent and natural limestone'.

demonstrated that the surface treatment would result in a concern with regard to the properties on the substance such that it would make the registration appropriate and necessary.

Nevertheless, the burden of proof rests with the company who wishes to make use of this exemption. The EU-based manufacturer or importer of surface-treated limestone that would not have registered the substance may be required by the competent enforcement authority to justify that the surface treatment process does not alter the toxicological properties of the substance and, therefore, it can still benefit from the Annex V exemption.

Suzanne WIANDT (DE) raised concerns regarding the association of the registration obligations with the inherent properties of a substance and highlighted that this is appears to be a precedent case. It was agreed that further discussions will take place bilaterally and/or within HelpEx to follow up this case.

## 1.9. Conclusions of the REACH Workshop

The Chair gave a summary of the key issues and thanked all correspondents, observers and presenters for their active participation in the morning session of the REACH workshop. He encouraged them to provide their feedback on the information available on ECHA's website, mainly on authorisation and restriction (see action points list – Annex I) and to respond to the online survey that will be provided after the event as ECHA wants to improve its services and thus their feedback is important for ECHA.

# 2. REACH-IT training

## 2.1. REACH-IT hands-on training

The aim of the hands-on training was to familiarise participants with the latest release of REACH-IT from an industry perspective.

The main changes introduced with the 3.1 release were first explained, and they consist of a:

- Revamped homepage, with the most important functionalities readily available for the users: Submit a dossier, Tasks (which replace the previous Messages for Action) and the Substance page, where registrants can monitor all the regulatory processes for a specific substance at a glance
- Revised Menu, where all the functionalities are displayed to support less experienced users in navigating the applications. The menu is split in thematic areas (Submission, Searches, Joint Submission, Company Management)
- Integrated helptext: examples of topic help, checklist and help pages where displayed

Participants then started the hands-on exercises covering the following actions in REACH-IT:

- Login as a company
- Change the company size to medium, to familiarise the participants with the new wizard for changing the company size
- Finding and joining a joint submission: the key message of this section being to make the participants aware of the possibility for users who have pre-registered, registered or inquired for a substance to see the existing joint submission for that substance before joining it. This feature also facilitates the contact of potential members with the lead registrants for the joint submissions they wish to join
- Submit a member dossier
- Check the task: this part is a key message for industry, since, from the introduction of 3.1, all the actions that a company is requested to perform within a given deadline, will be sent by ECHA as tasks and not as messages anymore. Examples of tasks are invoicing, draft decisions from evaluation, request for resubmission due to business rules failure
- Check the reference number page
- Consult the substance page

## 2.2. Questions & answers session

The main request from the participants was to get access to the testing environment to be able to see what industry sees when they log into REACH-IT. As the REACH-IT manuals are now integrated in the system that would allow them to directly answer questions they receive without the necessity to forward the questions to ECHA.

## Annex I – Action points

| Nr. | Action | A.P. | Person responsible in | | Due date | Action | Status |
|---|---|---|---|---|---|---|---|
| | | | NHD | ECHA | | | |
| 1. | - Feedback from HelpNet on questions received on AfA<br>- Feedback from HelpNet on AfA information on ECHA's webpages | 1.4 | All | Thierry NICOT<br>application-authorisation@echa.europa.eu | Mid-December 2016[66] | A document containing useful links to information and supporting material on the REACH authorisation process on ECHA's website was uploaded on S-CIRCABC on 18/11/2016, at: *https://webgate.ec.europa.eu/echa-scircabc/w/browse/c4f7e65e-9da6-492c-866c-a4942552f40c*<br><br>The survey on applications for authorisation (AfA) was launched on 18/11/2016: *https://www.webropolsurveys.com/S/591187FCC6917D4F.par* | Closed |
| 2. | Feedback on restrictions information on ECHA's webpages | 1.5 | All | Kirsi SIHVONEN<br>restriction@echa.europa.eu | End of November 2016 | | Closed |
| 3. | Brexit - possibly elaborating on answers for specific questions received by NHDs on the topic | Room document | DE | HelpNet Secretariat<br>help-net@echa.europa.eu | | | Closed |

[66] The deadline was extended to mid-December after the meeting.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 4. | Relation between the Annex III of REACH and the fee waiver | 1.8 | | ECHA to inform NHDs about the publication of the Q&A regarding the relation between the Annex III of REACH and the fee waiver | In due time | Q&A ('Who is entitled to a fee waiver?') **ID: 1237** published on ECHA website, at<br>https://echa.europa.eu/support/qas-support/qas | Closed |

# Annex II - List of participants

| **Country** | **Members of HelpNet** | | **REACH workshop** (04/10 am) | **REACH-IT training** (04/10 pm) | **FORUM training** (05-06/10) |
|---|---|---|---|---|---|
| Austria | SCHINDLER | Peter | X | X | |
| Bulgaria | BANDAKOVA | Teodora | X | X | X |
| Croatia | KAJIĆ | Silva | X | X | X |
| Cyprus | ORPHANOU | Maria | X | X | X |
| Czech Republic | KOLAR | Jan | X | X | X |
| Denmark | DYEKJÆR | Sidsel | X | X | X |
| Estonia | AMELKINA | Anna | X | X | X |
| Finland | TUHKUNEN | Sari | X | X | X |
| France | HAYAUD | Nathalie | X | X | X |
| Germany | WIANDT | Suzanne | X | X | X |
| Greece | CHATZIANTONIOU | Dimitrios | X | X | X |
| Greece | PANAGIOTA | Skafida | X | X | X |
| Hungary | NYITRAI | Viktor Péter | X | X | |
| Ireland | RODGERS | Karen | X | X | |
| Italy | GIANNOTTI | Francesca | X | X | |
| Latvia | JAUNKALNE | Natālija | X | X | X |

| **Country** | **Members of HelpNet** | | **REACH workshop** (04/10 am) | **REACH-IT training** (04/10 pm) | **FORUM training** (05-06/10) |
|---|---|---|---|---|---|
| Lithuania | KAIRYTE | Monika | X | X | X |
| Luxembourg | CHOCHOIS | Laurène | X | X | X |
| Norway | KJUUS | Berit Eyde | X | X | |
| Portugal | LAGINHA | Isabel | X | X | X |
| Slovakia | DANIHELOVÁ | Martina | X | X | X |
| Slovenia | MENARD SRPČIČ | Anja | X | X | X |
| Spain | ZAMORA NAVAS | Laura | X | X | X |
| Sweden | KRAMER | Helena | X | X | |
| The Netherlands | WOUTERS | Margaretha | X | X | X |
| UK | LLOYD | James | X | | |
| **Brussels** | **European Commission** | | **REACH workshop** (04/10 am) | **REACH-IT training** (04/10 pm) | **FORUM training** (05-06/10) |
| DG GROW | POPOVA | Temenuzhka | X | X | X |
| **Country/ Organisation** | **Observers** | | **REACH workshop** (04/10 am) | **REACH-IT training** (04/10 pm) | |
| Serbia | RASOVIC | Aleksandra | X | X | |
| CEFIC | JÁNOSI | Amaya | X | X | |

# Contributing ECHA staff

**Cooperation (A0)**

Andreas HERDINA

**Support, Forum & HelpNet Secretariat (A2):**

Johan NOUWEN, Pedro ROSELLO VILARROIG, Viorica NAGHY, Christina LOUKOU, Katarina CENDIC, Olena KRYCHEVSKA, Peter MEGAW, Daniele APE, Iris BRIAT, Tiina MULTASUO, Wanjiru NJOROGE

**Regulatory Affairs (B0):**

Jukka MALM

**Legal Affairs (B1):**

Minna HEIKKILA, Cyril JACQUET, Delphine GERBAUD, Christian SCHULTHEISS, Claire-Marie BERGERAT

**Registration (C0):**

Christel MUSSET, Laura WALIN

**Dossier submission & PIC (C1) – trainers :**

Lucia CONTI, Alexis QUINTANA-SAINZ, Javier SANCHEZ-SAEZ, Vasileios TSIFOUTIS, Margot MAGI, Terhi RANTALA, Soile NIEMI, Sandra ESTEVES MURRAS

**Substance ID and Data Sharing (C2)**

Jos MOSSINK, Bernadette QUINN, Pawel FIGIEL, Maia SOKOLOVA, Jonathan KUSTER

**Risk Management Implementation (D3):**

Matti VAINIO, Kirsi SIHVONEN, Thierry NICOT, Vasileios KOULOUMPOS

**Evaluation (E3):**

Ofelia BERCARU, Laurence HOFFSTADT, Eva VALKOVICOVA

**IT Infrastructure and support (I1):**

Vesa LEMINEN, Weria BARZINGI

**Corporate Services (R3)** - event assistants and conference operators:

Clemencia WIDLUND, Hilde Renate ERIKSEN, Joana ALBERTO, Anni HONKA, Marco POPOVIC, Konstantinos ANAGNOSTAKIS, Daniel STEVENS, Tero ALENIUS, Ari VALKEINEN, Oskari SALMI