

HelpNet REACH Workshop: summary of discussions

Time Tuesday 17 March 2015, 09:00 – 17:00

Place ECHA Conference Centre, Annankatu 18, Helsinki, Finland

1. Opening

The Chair of HelpNet, Andreas Herdina (ECHA), welcomed all REACH national helpdesks (NHDs) and observers to the REACH Workshop. The aim was to share the plans from ECHA towards the 2018 registration deadline and to tackle some specific topics such as the relevance and nowadays situation with the Small and Medium Enterprises (SME) verification task; Application for Authorisation (Afa) process; or the progress done in substance identification issues with specific industry sectors.

2. ECHA's REACH 2018 Roadmap - state of play

Presentation by Laura Walin (ECHA).

The Chair informed about the projects of a "Newcomers" section in ECHA website and the "Guidance on chemical safety" for SME, a product of the recently started cooperation with the European Enterprise Network (EEN).

3. German Helpdesk activities and experiences: Registration 2018

Presentation by Suzanne Wiandt (DE).

The participants discussed about the Frequently Asked Questions (FAQ): the usefulness of the ones published; their coverage of some aspects considered fundamental; and their review process which would be further discussed in the Steering Group meeting the following day.

The link to the Practical guide published by DE is the following:

http://www.reach-clp-biozid-helpdesk.de/de/Publikationen/Fachbeitraege/Fachbeitraege.html

4. HelpNet and REACH 2018: discussion on setting common goals

Presentation by Andreas Herdina (ECHA).

ECHA informed their plans to develop a manual or guide for companies struggling in data sharing activities. The data selection and cost data model would be based on the implementing act soon to be published by the European Commission (COM). In that sense ECHA expected that this act would make a direct link also between administrative costs and tonnage band, and that the data sharing disputes could be extended to joint submissions. ECHA also clarified their ongoing study on how to increase transparency in REACH-IT so all

members of a joint submission could know for which tonnage bands the other registrants had registered. Both legal and technical aspects had to be considered. The Chair, as member of the Directors' Contact Group (DCG), informed that they also were expecting the publication of the implementing act from COM to further develop their advice to SMEs.

An observer pointed out the situation taking place in many companies where the staff that have been responsible for pre-registration or registration in the early phases of REACH had already moved or left the company. It was frequently the case that the REACH knowledge was completely lost.

A correspondent commented on the workshop they organised in cooperation with EEN Norway targeting SMEs. They managed to gather downstream users but not registrants.

ECHA linked this event with the approach of inviting downstream users (DU) to push upstream the registration obligations. It was discussed the possibility of NHD contacting them and informing them about their rights in this respect, as well as using other networks such as EEN.

The Chair asked the correspondents to provide feedback on the "Checklist to hire a good consultant" which was under review at that point in time. He also asked the participants to further publicise it. Some of the correspondents suggested including aspects of experience in CLP and alternative methods.

5. SME benefits and SME verification under REACH

Presentation by Ivelina Tsocheva (ECHA).

ECHA explained some of the main mistakes that companies are making when assessing their size category and urged correspondents to pass some key messages to registrants prior to next deadline.

Some correspondents aired their concerns about the lack of transparency and predictability of the verification process. ECHA clarified that there is no legally specified moment for the initiation of the SME check as well as for concluding the verification process. ECHA explained that its aim is to issue a decision within a maximum period of three years from the initiation of each procedure and the whole process is highly dependent on the willingness of the company to cooperate. As companies have already benefitted from the fee reduction, they are normally uncooperative, making each case very time consuming and complex. In this respect, ECHA informed that it is currently working on updating REACH-IT for its next release so that companies have more guidance at the registration stage and before to claim any fee reductions.

6. Substance identity sector specific support – experience so far with the essential oils sector

Presentation by Hélène Jardin (ECHA).

In reply to questions from the participants, ECHA explained that these guidance documents were sector specific recommendations based on the same principles laid down in the original Guidance. The sector specific support was developed by Industry and not by ECHA as it was understood that the companies have deeper technical knowledge on the substances they manufacture. In spite of being developed by a certain national sector, this guidance could be applied to any other country with such industry. Finally ECHA pointed out that in this specific case the first challenge had been to make the producers aware that they were actually manufacturers under REACH.

7. Review of ECHA's Q&A Support

Presentation by Henna Piha (ECHA).

An observer suggested reviewing those FAQ that have been based on the idea of being on the safe side, as most probably time and experience had already shown which the correct answer was. A correspondent requested to include the new procedure in the Rules of Procedure (RoP) to ensure the transparency of the process, pointing out the need to keep or archive those that would become obsolete preventing the loss of knowledge.

A correspondent requested to go back to previous proposals that had been found as not suitable for FAQ and also unsolved Q&A pairs when looking for new FAQs.

ECHA agreed that when FAQ would be reviewed for editorial changes or made obsolete the HelpNet would be informed.

The HelpNet Secretariat agreed to include the review process, taking into account the feedback provided, in the RoP and later on ask the HelpNet for approval via written consultation.

8. Latest developments on applications for authorisation

8.1. Latest developments on exemptions and Q&As

Presentation by Markus Berges (ECHA).

A correspondent asked about the situation of phthalates in the authorisation list as they are now viewed by Member States as having an environmental hazard due to their endocrine disrupting properties but have been included in Annex XIV based on their reprotoxic properties (R 1B). ECHA clarified that indeed Rx 1B was not an environmental hazard. To include the endocrine disrupting properties an amendment to Annex XIV would need to take place.

Another correspondent asked if distinction should be made when the "equivalent level of concern" was related to human health or for the environment. ECHA agreed that indeed this distinction is important as exemptions from the scope of authorisation can be based on the fact that the substance was identified only because of hazards to the human health (Article 56, 5).

8.2. Main outcomes of the AfA lessons learnt conference held on 10-11 February

Presentation by Markus Berges (ECHA).

ECHA explained that the inclusion in the Stockholm Convention on Persistent Organic Pollutants (POP) of DHPDC had already been taken into account in the official opinion issued by ECHA, which had already been published. They also pointed out that as an outcome of the questionnaires regularly sent to applicants there was a slight yet still significant downwards trend on application costs.

A correspondent raised the question about the perception that Non-Governmental

Organizations (NGOs) had of the help provided by ECHA to applicants. ECHA replied that in their view it was well justified and the intention in the first place is to make the work of the Committees easier and smoothing the process in general; and in particular was a share of work that would have to be done at some point by them.

Another correspondent requested information about the fast track consultation launched for a HelpEx question (refer to Annex II – Action points list).

8.3. Pre-configured IUCLID 5 for AfA

Presentation by Vasileios Kouloumpos (ECHA).

No questions were raised regarding this agenda point.

8.4. Article 66 downstream user notifications

Presentation by Vasileios Kouloumpos (ECHA).

A correspondent suggested that a leaflet could be produced and used by inspectors and NHD in order to support the campaign to be launched by ECHA on the duty of downstream users of authorisation holders to notify.

ECHA explained that the IT system would provide a proof of submission valid for inspectors and would also issue a reminder on the requirement for safe use. ECHA agreed to include further information in its newsletter as soon as a respective webpage has been published at its website.

9. Substances in articles awareness programme

Presentation by Telmo Jorge Vieira Prazeres (ECHA).

In reply to a question from a correspondent, ECHA explained that the way to access the future materials' information platform was under investigation in the ongoing feasibility study. However, it is a critical aspect that it should be useful and friendly to Industry to ensure its success. Preferentially, it should be public with a webpage interface. It was further explained that the Materials' Information Platform (MIP) approach, which is focused on materials, would not be affected by European Court of Justice ruling on the 0.1 % w/w problem.

10. Questions on meeting documents

10.1. Latest on restrictions

No questions were raised for this document.

10.2. ECHA's compliance check strategy

ECHA acknowledged that a large number of substances subject to compliance check were UVCB. Therefore an assessment project in cooperation with Member states (MS) had been

initiated to agree on the approach to be taken.

10.3. ECHA's substance identity strategy

In reply to a question from a correspondent, ECHA explained that the focus would be placed on cases were deviations from the standard requirements had been used without any justification, which could amount to 20% of the cases. Furthermore, this section would be modified in the next version of IUCLID in the hope that the quality of the information would improve, consequently reducing the number of dossier to be manually checked.

11. HelpNet collaboration on downstream user topics

11.1. Update on downstream users topics

Presentation by Fesil Mushtaq (ECHA).

A correspondent pointed out that they were missing a DU icon in the home page of ECHA. They also reminded the other participants that formulators have obligations not only under REACH but also under CLP.

11.2. Using REACH data for other EHS legislations

Presentation by Monique Pillet (ECHA).

ECHA highlighted their objective to find examples on the evolution of safety data sheets (SDS) from pre-REACH to 2015.

11.3. Integration of REACH and EHS

Presentation by Bridget Ginnity (ECHA).

A correspondent expressed their positive interest in the integrated support also with other chemical and environmental legislation. Other too supported the shift in the point of view to that of the worker. Four correspondents already worded their interest in participating in the focus group. Some correspondents expressed their interest in the "REACH Tips" and asked for their translation. The ideas of launching new surveys or releasing more documents were not welcomed.

ECHA agreed to circulate in written the questions placed in the three agenda points to allow participants some time to better reflect on them, as well as on their participation on the focus group on DU issues related to other EHS legislation.

The Chair agreed to include DU information on the regular HelpNet update.

12. Closing of the meeting

The Chair thanked all correspondents, observers and presenters for their participation. The Chair encouraged the correspondents to provide their comments on the documents that would be made available to them (see Action Points list – Annex II) and come up with ideas and topics for future workshops.

Annex I - List of participants

Members of HelpNet

Austria: KRATZ Karin

Belgium: FEYAERTS Jean-Pierre GAIGUROVA Margarita

Croatia: KAJIC Silva, LOVRIC Zdravko

Cyprus: ORPHANOU Maria

Czech Republic: KOLAR Jan
Denmark: DYEKJÆR Sidsel
Estonia: AMELKINA Anna

Finland: PRIHA Maarit, TUHKUNEN Sari

France: DUFFORT Gaëlle
France: PIGANIOL Nathalie
Germany: WIANDT Suzanne

Greece: CHATZIANTONIOU Dimitrios

Hungary: NYITRAI Viktor

Ireland:COLLINS Karen, WALSH CarolineItaly:GIANNOTTI Francesca, IZZO PaoloLatvia:LAZDEKALNE Elina, RUBENE Liga

Lithuania: GRINCEVICIUTE Otilija

Luxembourg: BIWER Arno, CHOCHOIS Laurene

Malta: ANASTASI Audrey Anne The Netherlands: WOUTERS Margaretha Norway: TVERMYR Marianne Poland: DOMANSKI Krzysztof **Portugal:** LAGINHA Isabel **CAROLE Nicoleta** Romania: Slovakia: SLIMÁKOVÁ Anna MENARD SRPCIC Anja Slovenia:

Spain: SANCHEZ DIAZ Maria Elena, ZAMORA NAVAS Laura

Sweden: KRAMER Helena

Representatives of the European Commission

DG ENV: Absent
DG GROW: Absent

Candidate country observers

Serbia: GRUJIC Jelena, RASOVIC Aleksandra **Turkey:** OZGUN Pinar, TIRYAKI Ozlem Ilknur

Observers

CEFIC: AMAYA Jànosi **CEPE:** TURKENBURG Luc

ECHA staff

Representing the Units: A2, C0, C2, D3, D2, E3, R1 **Annex II Action points**

Nr	Action	Actor	Due date
1	Provide feedback on DCG paper on "Checklist to hire a good consultant"	NHD	30 April
2	Include review process of FAQ in the RoP of HelpNet to improve transparency	HelpNet Secretariat	30 April
3	Reflect revision of FAQ in HelpEx (aspect to be included in RoP).	HelpNet Secretariat	Per phase
4	Consider "not suitable as FAQ" and "unsolved" Q&A pairs for review of FAQ for R2018 (aspect to be included in RoP)	HelpNet Secretariat	30 April
5	Clarify the outcome of FAQ fast track consultation for HelpEx question 7381	HelpNet Secretariat	30 March
6	Include article on Article 66 notification in next HelpNet newsletter to allow NHD raising awareness	HelpNet Secretariat	By publication of newsletter
7	Reply to questions from Fesil, Monique	NHD correspondents	HelpNet update, 30 March
8	Request "REACH Tips" translated into National language after circulation	NHD correspondents	HelpNet update, 15 April
9	Volunteer for focus groups on DU (scoping discussion)	NHD correspondents	HelpNet update, 15 April
10	Nominations one per MS for Communicators' Network	NHD correspondents	HelpNet update, 15 April
11	Linked in as a communication means or CIRCABC		