The 17th HelpNet Steering Group meeting

The 17th HelpNet Steering Group meeting, organised for the members and observers of HelpNet, took place on 26 October 2022, in Helsinki.

This document summarises the topics discussed[1] during the 17th Steering Group meeting (Annex I), the follow-up action points (Annex II) and results of the polls (Annex III). The names of the participants attending the event are listed in Annex IV to these minutes.

1. Opening the Steering Group meeting

1.1 Opening by the Chair of HelpNet

The Chair, Erwin ANNYS (ECHA, Head of Unit Support and Enforcement) opened the 17th Steering Group meeting and welcomed representatives of national helpdesks, observers from candidate and third countries, observers from industry and additional experts.

The Chair introduced the changes in the unit and directorate: Evelyne FRAUMANN and Francesco FACINCANI joining the unit and highlighted the upcoming changes in the senior management. He then gave the floor to Mercedes VIÑAS, Director of Submissions and Interaction.

Mercedes VIÑAS opened the Steering Group meeting thanking the national helpdesks for the cooperation since the network was established in 2007 and during the pandemic years. Having the national helpdesks well informed and engaged in ECHA's activities is key for the correct functioning and implementation of chemicals legislation.

She acknowledged the increase of questions redirected to the REACH and CLP national helpdesks, due to the new ways of working and thanked the national helpdesk for the constant effort and cooperation, the latter also enhanced through the REACH and CLP video conferences organised by the Secretariat during the last year.

She also outlined the work to be expected with the future tasks ECHA might get, gave her insight on the Chemicals Strategy for Sustainability and emphasised the need for further cooperation within the network.

1.2 HelpNet 17 - follow-up of action points

The Chair presented the list of action points from the previous Steering Group meeting in November 2021. Out of two ongoing action points, one remains open and one will be closed with the presentation 3.2 New tool for Q&As.

1.3 Approval of the HelpNet 17 draft agenda

The Chair introduced the draft agenda which was adopted without further comments. He requested the HelpNet members to verbally express their concerns[2] (if any) on the attendance of observers or invited speakers at particular agenda points. No objections were raised.

[1] Disclaimer: Note that the text of the BPR, CLP and REACH regulations is the only authentic legal reference and that the summaries in this document do not constitute legal advice. For further advice, contact your national helpdesk.

[2] According to the Handbook, section 1.2 Chair of the HelpNet Steering Group, the 'Chair considers and takes decisions on any objections from members to the participation of observers or additional experts.

2. Updates from the HelpNet Secretariat

2.1. ECHA preparing for new tasks

Erwin ANNYS (ECHA) gave an update on the actions taken after the adoption[3] of the European Commission's Chemicals Strategy for Sustainability[4] (CSS) towards a toxic-free environment.

ECHA started operations in June 2007 when REACH entered into force. Since then, new tasks were given to ECHA when the CLP[5], BPR[6] and PIC[7] regulations entered into force.

Other activities were added to the portfolio of ECHA being:

- the chemicals in products, better known as SCIP - the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD);
- activities related to Poison Centres (Article 45 of CLP);
- work on European Union Observatory for Nanomaterials (EUON) with information about nanomaterials on the EU market;
- tasks[8] on persistent organic pollutants (POPs);
- work[9] compiling a list of substances that can be safely used in materials that come into contact with drinking water;
- a mandate to look at the occupational exposure limits for workers.

The European Green Deal is the European Commission's ambitious plan for climate and environmental-related challenges aimed at turning the EU into the first climate neutral continent by 2050. To achieve these objectives and to better protect citizens and the environment from dangerous chemical products, a revision[10] of REACH and CLP was also announced (see Commission Q&A on the Chemicals Strategy).

The activities that may further come to ECHA are the Battery Regulation (with one expected restriction per year), Industrial Emissions Directive (work starting from 2024), the EU Common Data Platform for Chemicals – to be established in 2025 but with work starting already in the beginning of 2023.

Finally, the Chair acknowledged that many of the new ECHA tasks would probably not be in the portfolio of the REACH, CLP and BPR national helpdesks in various countries, but this can be discussed at a later stage.

2.2. EFSA presentation

Elina CIEKURE and Sara DE BERARDIS (EFSA) introduced the work and the questions within their remit, how they address questions, their interactions with stakeholders and institutions.

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[3] On 14 October 2020.
[4] https://environment.ec.europa.eu/strategy/chemicals-strategy_en
[5] Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP) entered into force on 20 January 2009.
[6] Biocidal Products Regulation (BPR) entered into force in July 2012.
[7] Prior Informed Consent Regulation (PIC) entered into force on 1 March 2014.
[8] https://echa.europa.eu/-/echa-starts-work-on-persistent-organic-pollutants
[9] https://echa.europa.eu/-/echa-starts-work-on-making-drinking-water-safer
[10] See the presentations given by Riccardo Zorgno and Jéremy Pinte from the European Commission (DG GROW) at the REACH and CLP workshops (minutes available at: https://echa.europa.eu/about-us/partners-and-networks/helpnet/2022

Discussion

Representatives of NHDs were very appreciative of the presentation. One NHD stated that they were unaware of the existence of other helpdesks from other agencies and asked what EFSA is doing in case of overlapping regulations (for example in case of overlapping in classification of substances). Sara DE BERARDIS replied that EFSA is indeed replying only to questions withing their remit and in cases of questions related to CLP they redirect the customer to ECHA and do not formulate any reply.

The second question was related to the legal area of activities and whether EFSA has clear responsibilities with respect to the the national authorities and if there are special agreements and existing (supporting) helpdesks. Sara DE BERARDIS replied that there is no provision in the legislation setting a direct interaction with national authorities (there is no structure similar to HelpNet). There is a clear distinction between what is in EFSA's remit and what is not. As an example it was mentioned that in the case of the classification of novel foods, only after the competent authority confirms the need for an application for authorisation, will EFSA support the requester.

Elena BIGI thanked EFSA for their presentation and reinforced that the cooperation between the sister agencies stemmed from the overlapping type of questions and sometimes back and forth exchange between EFSA, ECHA and the Commission. She also mentioned that the purpose of these collaboration meetings between sister agencies is to exchange best practice.

The last question was regarding the grant and support from competent organisations and from which sector they come from, private or public. Sara DE BERARDIS replied that the grant was targeted at competent organisations from MSs that have knowledge on the applications for authorisation of regulated products. The purpose was to establish communication with universities for example and share knowledge on the application for authorisation process. Unfortunately, the call did not yield any results.

2.3 EMA presentation

Efstratia VATZAKI and Elfa EIHENBAUMA (EMA) introduced EMA's work related to the request for information (RFI) and access to documents and the questions within their remit, how they address requests, the interactions with stakeholders and their communication channels and transparency's efforts.

Discussion

One NHD made a comment to all three agencies on whether the collaboration is supported by the Commission and directors as the NHD would like to cooperate with other national authorities but the ministry from the respective country is not yet in favour of it. The collaboration between the agencies would set a good example and open the door to new cooperation between the NHDs and other competent authorities and it will be brought forward as such.

Elfa EIHENBAUMA replied that EMA would be very much in favour of new collaborations. Currently, there is a wide network of European experts from the scientific committees who contribute to the evaluation of medicines and EMA could consider expanding this and improve on how information is requested and exchanged, as the collaboration of the three sister agencies has been very beneficial so far.

2.4 Limited scope of competences - the German helpdesk perspective and approach

Heinz BÜLTER (German Helpdesk) introduced the scope of competences of the German Helpdesk and how they deal with enquiries they receive that go beyond this scope.

The responsibility of the German Helpdesk is limited to REACH, BPR and CLP. However, enquirers are not always aware of the legal situation and the different responsibilities when it comes to chemical regulations. As a result, the German Helpdesk receives enquiries related to other topics beyond their remit and, in such situations, they aim to support the enquirer as much as possible, within their scope of possibilities. The following solutions and examples were presented:

- Referring to competent authorities, using specific IT tools (ICSMS database) or contact lists.
- Referring to guidance, Q&As and other material published online (e.g. on the ECHA website).
- Preparing and setting up dedicated web pages for specific topics (e.g. SCIP).
- Being part of a working group to develop national FAQs.

For mixed enquiries that include questions both within and outside their remit, the German Helpdesk indicated that they reply thoroughly on the elements that are under their scope of competences and refer to available guidance or other competent authorities for the remaining questions.

After a poll, other national helpdesks were invited to share their experience on whether they are facing similar issues and if so, how they deal with such situations. See the results of the poll in Annex III.

Discussion

One NHD noted that they are responsible for four pieces of legislation and answer questions related to REACH, CLP, the Detergents Regulation and PIC indicating that they are facing very similar situations to that noted by the German HD. They also often receive questions outside their scope of competences but are willing to help the enquirer as much as they can. They have an internal database listing agencies, departments, and contact details for all different pieces of chemicals legislation. It is an important effort to keep this database up to date but worth it as it enables them to redirect the enquirer to the appropriate competent authority. Another NHD supported the information shared by these NHDs.

3. Updates from the HelpNet Secretariat

3.1 New BPR observer in the HelpNet

Türkiye is one of the beneficiaries of ECHA's IPA project entitled 'Preparatory measures of future participation of candidate countries and potential candidates in the work of the European Chemicals Agency in implementing REACH, CLP, BPR, PIC and POPs' in the remit of ECHA and funded by the European Union.

In this context, on 13 September 2022, representatives of the Ministry of Health of the Republic of Türkiye submitted their application for membership in the BPR work of HelpNet. Türkiye already has an observer status in HelpNet for CLP and REACH.

The Chair introduced Okan KUMCU – chemical engineer at the Ministry of Health, the General Directorate of Public Health – who presented the support activities provided by his

competent authority to industry. He explained how the helpdesk is organised, and the role of the four sub-units of his department regarding biocidal product authorisation or biocidal active substance registration enquiries:

- Disinfectant Unit (product types 1-5)
- Preservatives and other biocidal products Unit (product types 6-13 and 21)
- Pesticide Unit (product types 14-18)
- Market Surveillance and Inspection Unit (all product types)

He then presented the structure and the content of the website[11] and provided links to supporting materials such as the list of active substances and three different lists of biocidal products – depending on their status[12].

Finally, Okan KUMCU expressed the readiness to join the HelpNet as a new BPR observer. Following the favourable outcome of the voting procedure (see results in Annex III), the Steering Group officially accepted the Turkish Ministry of Health as a new BPR observer (results of the poll in Annex III).

Action point

Update the contact details for the Turkish Ministry of Health on the ECHA website once the new Turkish BPR observer confirms with the Turkish Medicines and Medical Devices Agency under the Ministry of Health.

3.2 New tool for Q&As

Roxana BROASCA (ECHA, Support and Enforcement Unit) gave an update on the Q&A tool.

ECHA released a new Q&A search page[13] on the website on 10 October 2022 to improve the service to customers and streamline the Q&A review process. The new database supports multiple selection search so users can easily find the answer to their question. The questions agreed with the national helpdesk are now marked in the NHD column. There is a demo/tutorial[14] that was made for the NHDs.

The presentation covered timelines of the Q&A project and touched upon the most important highlights of the new Q&A search tool. Michael GEORGOPOULOS (service manager from Directorate I) gave a brief technical presentation on how a revision is done in the internal tool and listed the main advantages of using it. The end of the presentation was a short live demonstration showcasing the new elements of the tool.

Discussion

The questions received from the audience were related to the possibility of sharing the link to an individual Q&A, export possibility, and sharing the results of a search. Another question was making reference to the fact that the drop down scope list is visible in certain browsers. The Q&A tool only supports Microsoft Edge and Chrome browsers, not Mozilla.

Action points

Follow up the option to provide Q&As links to a specific question and links directly to scopes/groups of Q&As with the ECHA contractor. This is planned for January 2023.

[11] https://hsgm.saglik.gov.tr/tr/cevresagligi-anasayfa
[12] Registered Products List (Available on the market until 31/12/2023 after which it must apply for a authorization), List of Authorised Biocidal Products, List of Biocidal Products without active substance
[13] https://echa.europa.eu/support/qas
[14] https://www.youtube.com/watch?v=4NByT1w1EjM

Facilitate the possibility to extract Q&A search content from the new Q&A tool. This is a new feature that should be enabled once the technical details will be in place as confirmed by Michael GEORGOPOULOS.

3.3 HelpNet updates

Viorica NAGHY (ECHA, Support and Enforcement Unit) introduced the revision of the HelpNet Handbook[15], HelpNet newsletter, and the upcoming annual survey on helpdesk activities.

In 2016, the rules of procedure of the HelpNet Steering Group, the mission statement, the operating procedures and the step-by-step guide on the publication of frequently asked questions (FAQs) on the ECHA website – the one addressing issues[16] out of the remit of the network – were merged into one document which is now the Handbook of the HelpNet.

The previous revision, taking place in 2020, introduced a disclaimer stating the responsibility of the national helpdesks (NHDs) for the advice they give; updated the definition of function and expertise of the Chair and alternate; and introduced the term of virtual meeting as a contingency.

The three main changes proposed by ECHA in 2022 are the following:

- The cooperation on matters falling within the mutual interest and mandate of HelpNet could include new tasks in the scope of the Chemicals Strategy for Sustainability.
- Replace 'consensus' by 'agreement of a two-thirds majority of the voting HelpNet members'.
- Simplify the FAQ procedure by removing the cut-off dates and consider the start of an FAQ procedure every time a new FAQ is proposed. Also, reopen an FAQ proposal for comments only when agreement is not achieved in the first step.

The Chair highlighted that replacing 'consensus' by 'agreement of a two-thirds majority of the voting HelpNet members' would align the voting system in HelpNet with the ECHA Management Board.

The Chair opened a poll seeking the HelpNet members' opinion on the changes proposed. As members asked for more time for reflection, the Chair informed that a written procedure will be launched in the following week to seek members' approval of the changes proposed by ECHA, item by item.

Viorica NAGHY introduced the HelpNet update (structure, content, and the frequency), the annual survey, and its expected timelines. Feedback on the newsletter and the survey can be provided through the satisfaction survey to be launched after the meeting.

Finally, participants unanimously agreed to have the 18th Steering Group meeting organised as a physical meeting in spring 2023 (see results of the poll in Annex III).

Action point

Launch a written procedure for the approval of the different proposals made for the Handbook of HelpNet.

[15] The draft Handbook – with proposals visible in track changes - was uploaded in S-CIRCABC before the meeting. Path: /CircaBC/echa/HelpNet/Library/02 Steering Group/General documents.

[16] The SOS questions standing for **S**till **O**pen **S**ubject.

4. Updates on ECHA activities

4.1 Forum activities

Maciej BARANSKI (ECHA, Support and Enforcement Unit, Team Leader of the Harmonised Enforcement Team) presented the priorities of the Forum, starting with the cross-cutting activities and finishing with the work related to the Chemicals Strategy for Sustainability (CSS).

The REF-8 project on internet sales of chemicals had shown an alarming level of non-compliance and, as a follow-up, the Forum developed a guide for inspectors and provided the Commission with recommendations on how legislative change could improve compliance. Under the REF-10 project on integrated enforcement, inspections are ongoing and 200 inspectors were trained. The manual of conclusions updated in this context would be of interest to the national helpdesks.

Focusing on REACH, the Forum had delivered their advice on the enforceability of eight restriction proposals and was discussing the transparency of the advice and update of the process. Maciej BARANSKI also mentioned the ongoing REF-9 on authorisations, with the report expected to be published in February. Up to 500 substances were checked, with a focus on downstream users. There was also a major issue with compliance in this area – ~26% of substances were used in breach of conditions.

Maciej BARANSKI then presented the pilot project related to recovered substances. The inspectors needed to identify whether the recovered material was an actual substance in the meaning of REACH and found that ~26% of recovered substances missed a required registration. The REACH project in preparation is REF-11 on safety data sheets, focusing on the amended Annex II. The training will take place in November and the HelpNet correspondents were welcome to participate remotely.

Moving on to CLP, there was an on-going pilot project on mixture classification, and more specifically on Article 9 regarding the use of the bridging principles, expert judgement and weight of evidence. The work was organised around specific case studies rather than the normal operational phase. Maciej BARANSKI highlighted the close cooperation with the Commission as the project touched upon a grey area in the legal text.

Under the BPR, the key project was BEF-2 on control of authorisation and presence of approved substances. Up to 365 inspectors had been trained with many of them becoming multipliers. On 2 December another training event would take place covering CLP, *in situ* generation and borderline issues. The HelpNet correspondents were invited to attend this event, too.

The final part of the presentation dealt with the input provided to the Commission in the context of the CSS, and more specifically the zero tolerance approach to non-compliance. The Forum had provided input on the European audit capacity and will discuss proposals on strengthening import control, where custom authorities need to be heavily involved. Overall the feedback provided to the Commission was constructive.

Discussion

Maciej BARANSKI clarified, after a question from one NHD, that 26 % of the breaches in the case of recovered substances (pilot project) were related to the impossibility to properly identify the recovered substance because the company could not demonstrate sameness with an existing registration. The conclusion of the inspectors was then that the company was non-compliant. He also clarified that the focus of REF-10 was on materials and product categories common for consumer products such as fashion products, textiles, electronic

equipment, toys, sport articles and household articles, but could not provide further details at this point of the project because controls are still ongoing. The list of products and materials covered will be included in the project report.

Action point

Invite the REACH and BPR HelpNet correspondents/alternates to the Forum 'Training for trainers' on Safety Data Sheets from 24 to 25 November; and 'CLP for biocides, *in situ* generation systems and BPR borderline issues' on 2 December 2022.

4.2 Communication activities

Tiiu BRÄUTIGAM (ECHA, Team Leader of News and Media in the Communications Unit) presented the latest and most important communication activities relevant for HelpNet.

This year, ECHA communicated on several hot substances – glyphosate, lead in outdoor shooting and fishing, per-and polyfluoroalkyl substances[17] (PFASs); was preparing for the chemicals strategy and its impact on ECHA's work; and kept raising awareness on social media and preparing podcasts on safer chemicals.

ECHA started in 2022 preparing a series of podcasts[18] – presenting expert views on chemical safety in the EU, featuring both ECHA's experts and partners' views. The most popular themes were: grouping of chemicals, bisphenols, SCIP database, RAC/SEAC meeting outcomes.

In 2023, communication activities will continue focusing on PFAS; the restriction proposal prepared by The Netherlands, Germany, Denmark, Norway and Sweden will come to ECHA in January 2023. On the chemicals strategy, once the CLP and REACH revisions are finalised, ECHA will start preparing targeted advice for companies. Also, new tasks expected by ECHA will bring new stakeholders and new areas to communicate about.

The Safer Chemicals Conference planned for autumn 2023 is targeted to industry stakeholders and will take place in Helsinki, possibly with some hybrid elements. The event will include topical sessions, keynotes, panel discussions, case studies and the possibility to meet and network with ECHA experts.

ECHA has been communicating actively through social media - LinkedIn, Twitter, Facebook and Instagram. Together with the European Food Safety Authority (EFSA), European Environment Agency (EEA), European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), ECHA started a joint project on Instagram: One Health One Environment EU. Together with the sister agencies, we post about what the EU is doing to protect people's health and the environment.

Last but not least, ECHA is looking forward and preparing to onboard the new Executive Director, Dr Sharon McGuinness on 1 December 2022.

Discussion

One NHD expressed their appreciation regarding ECHA's communication activities and referred to the hot topics page which was found very useful (e.g. restrictions and timeframes). Tiiu BRÄUTIGAM clarified that information available on ECHA's web pages is translated only when the information remains stable for more than 6-12 months.

[17] https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas
[18] Podcasts are available at: https://echa.europa.eu/podcasts

Action points

National helpdesks to share ECHA's materials on their social media channels.
ECHA can also promote national campaigns (e-mail to: social-media@echa.europa.eu).

5. Collaboration activities

5.1 New way of working (NWOW) after one year

Elena BIGI (ECHA, Support and Enforcement Unit, Team leader of REST) gave an update on the new ways of working (NWOW) after one year, specifically on the number of REACH and CLP enquiries redirected to NHDs.

The NWOW was kicked off on 1 September 2021 for EU-related questions and 6 October for non-EU ones. Questions related to the SCIP database and PIC questions remained mainly in ECHA's remit. More, the BPR division of tasks remained unchanged. After a reflection on the reason why this division of competence was introduced due to a Management Board reprioritisation of ECHA's activities, Elena BIGI presented statistics that showed an average of between 20 to 29 % of questions being redirected to the National Helpdesks.

Moreover, Elena BIGI outlined the main tools for cooperation: video conferences (VCNs), support material, trainings, ad hoc working groups. Feedback was asked to our NHDs on how they have felt this year (increase of questions, cooperation etc).

Discussion

One NHD outlined that the number of BPR questions from non-EU had increased during the summer and asked whether it is the same for ECHA. This was noted as an action point as ECHA needed to check the trend.

Participants confirmed the usefulness of the video conferences. Another participant asked whether it is possible to check within the HelpEx the questions discussed in the VCNs, and ECHA confirmed that this is not possible at the moment, but questions are kept and searchable in the excel table uploaded in S-CIRCABC.

Another NHD outlined the difference between the video conference and the HelpEx that is still very much appreciated as it gives more time to reflect on questions, video conferences being more immediate. ECHA replied indeed that both complement each other, and that nothing forbids to also bring pending HelpEx questions in the video conferences, and that HelpEx will be of course kept as a tool for discussion.

Another NHD welcomed the possibilities to combine both formats and use the video conferences to discuss long time pending HelpEx questions.

The Chair concluded outlining that ECHA will look into possibilities for improving the process and welcome all the received feedbacks.

Action point:

Check BPR trends for EU versus non-EU questions and report back.

5.2 Report from the Borderline Working Group

5.2.1 Report from the Borderline Working Group

Evelyne FRAUMAN (ECHA, Support and Enforcement Unit) presented the outcome of the Working Group assessing borderline cases on the article definition. The Borderline Working Group (BWG) work started in March 2021 and continued throughout 2022. The BWG was established to discuss difficult questions received by NHDs and ECHA on the article definition. One of the objectives of the BWG is to create a catalogue of borderline case assessments for publication as a HelpNet document to help duty holders and authorities in the assessments.

The BWG members agreed on about 20 case assessments to be included in the catalogue. The catalogue format was presented: the overview of agreed cases presents a description of the object to be assessed, the assessment conclusion and a link to the detailed assessment in annex. It also suggests similar cases to allow for evaluating the possibility to extend the reasoning for other similar objects. Cases related to each other, i.e. in similar categories, are clustered in the catalogue.

5.2.2 Report from the Borderline Working Group activities and mandate extension [CLOSED SESSION]

Closing of the HelpNet Steering Group meeting

The Chair listed the action points as the outcome of the meeting. He thanked the presenters for their contributions and interesting presentations, and all participants for the interesting discussions that had taken place. He invited participants to reply to the satisfaction survey that is to be sent after the meeting.

Annex I – Agenda

17th HelpNet Steering Group meeting

1. **Opening the Steering Group meeting** (9:00-10:15)
   1.1 Opening by Mercedes VIÑAS, Director of Submissions and Interaction
   1.2 HelpNet 16 - follow-up of action points
   1.3 Approval of the HelpNet 17 draft agenda
2. **Updates from the HelpNet Secretariat and sister agencies** (10:15-11:35)
   2.1 ECHA preparing for new tasks (ECHA, Erwin ANNYS)
   2.2 EFSA presentation (Elina CIEKURE, Sara DE BERARDIS)
   2.3 EMA presentation (Efstratia VATZAKI, Elfa EIHENBAUMA)
   2.4 Limited scope of competences - the German helpdesk perspective and approach (Germany, Heinz BÜLTER)
3. **Updates from the HelpNet Secretariat** (12:00-13:00)
   3.1 New BPR observer in the HelpNet (Türkiye, Okan KUMCU)
   3.2 New tool for Q&As (ECHA, Roxana BROASCA)
   3.3 HelpNet updates (ECHA, Viorica NAGHY)
4. **Updates on ECHA activities** (14:00-15:00)
   4.1 Forum activities (ECHA, Maciej BARANSKI)
   4.2 Communication activities (ECHA, Tiiu BRAUTIGAM)
5. **Collaboration activities** (15:30-16:15)
   5.1 New way of working (NWOW) after one year (ECHA, Elena BIGI)
   5.2 Report from the Borderline Working Group (ECHA, Erwin ANNYS, Evelyne FRAUMAN)
   5.2.1 Report from the Borderline Working Group and presentation of the catalogue [OPEN SESSION]
   5.2.2 5.2.2 Report from the Borderline Working Group activities and mandate extension [CLOSED SESSION]

   Conclusions of the day (16:15-16:30)

Closing the Steering Group meeting

Annex II - Action points

17th HelpNet Steering Group meeting

No	Action	Agenda item	Responsible	Status
1.	Update the contact details for the Turkish Ministry of Health on the ECHA website once the new Turkish BPR observer confirms with the Turkish Medicines and Medical Devices Agency under the Ministry of Health.	3.1	ECHA Turkish BPR observer	Closed
2.	Follow up with ECHA contractor the option to provide Q&As links to a specific question filtered in the Q&A page and links directly to scopes/groups of Q&As.	3.2	ECHA	Ongoing
3.	Facilitate the possibility to extract Q&As from the new Q&As tool.	3.2	ECHA	Ongoing
4.	Launch a written procedure for the approval of the different proposals made for the Handbook of HelpNet.	3.3	ECHA	Closed
5.	Invite the REACH and BPR HelpNet correspondents/alternates to the Forum 'Training for trainers' on Safety Data Sheets from 24 to 25 November; and the 'CLP for biocides, *in situ* generation systems and BPR borderline issues' on 2 December 2022.	4.1	ECHA	Closed
6.	Share ECHA's materials through your social media channels.	4.2	NHDs	Ongoing
7.	ECHA can also promote national campaigns (inform us by e-mail: social-media@echa.europa.eu).	4.2	NHDs	Ongoing
8.	Check BPR trends for EU versus non-EU questions and report back.	5.1	ECHA	Closed

Annex III – Poll questions and results

17th HelpNet Steering Group meeting

Agenda item 2.4 - Limited scope of competences - the German helpdesk perspective and approach

How many regulations/legal areas does your helpdesk covers?	
A. Three	**12**
B. Between 4 and 6	**5**
C. More than 6	**3**

Agenda item 3.2 - New BPR observer in the HelpNet

Do you agree with Türkiye becoming a BPR observer ?	
A. Yes	**22**
B. No	**2**

Agenda item 3.3 - HelpNet updates

Do you agree scheduling the 18th Steering Group in May or June 2023, in Helsinki?	
A. Yes	**22**
B. No	**0**

Agenda 5.2.2 - Report from the Borderline Working Group activities and mandate extension

Do you agree extending the mandate of the BWG until spring 2024?	
A. Yes	**23**
B. No	**0**

Annex IV – List of participants

Country	Name
Austria	Barbara WETZER
	Peter SCHINDLER
Belgium	Kristof CLAES
	Daphné HOYAUX (remote)
Bulgaria	Zvezdelina PETROVA
Cyprus	Maria PALEOMILITOU
	Maria ORPHANOU
Croatia	Tajana KOVACEVIC
	Zdravko LOVRIC
	Ivana VRHOVAC FILIPOVIC
	Romana GRIZELJ (remote)
Czech Republic	Jan KOLAR
	Jarmila SLADKOVA (remote)
Denmark	Maria THESTRUP JENSEN
	Sehbar KHALAF
	Helle HUSUM (remote)
	Lone KÆRGAARD (remote)
Estonia	Riina LAHNE
	Aigi LAHE
	Anna AMELKINA
Finland	Hannu MATTILA
	Sari TUHKUNEN
	Tarja KARLEMO (remote)
France	Nathalie HAYAUD
	Gaëlle DUFFORT
Germany	Anja HACKMANN
	Heinz BÜLTER (remote)
	Juliana REY (remote)
Greece	Eleni FOUFA (remote)
Hungary	Eszter GÁBOR
	Henrietta SZABO
	Nikoletta MAROSVÖLGYI (remote)
	Tamas KOVAC
Ireland	Majella COSGRAVE
	Louise PIERCE (remote)
	Margarete HOULIHAN (remote)
Italy	Antonina LONGO (remote)
	Fabio CAPORALE (remote)
	Francesca CARFI

Italy	Silvia ALIVERNINI
	Maria ALESSANDRELLI (remote)
	Renato CABELLA (remote)
	Sabrina MORO IACOPINI (remote)
	Sonia D'ILIO (remote)
Iceland	Fífa KONRADSDOTTIR (remote)
Lithuania	Agne JANONYTE (remote)
	Beata VOLUJEVIC
	Jurgita BALČIŪNIENĖ
Luxemburg	Laurène CHOCHOIS
Latvia	Sandra MATISA
	Evija PORIKE
Malta	Nathanael ELLUL
Netherlands	Cindy VAN DER MEER
	Femke AFFOURTIT (remote)
	Peter VAN IERSEL (remote)
Norway	Elena KLÅPBAKKEN DRØNEN
	Cécile BLOM
	Jorid FRYDENLUND
Poland	Łukasz BELKIEWICZ
	Kristof DOMANSKI (remote)
Portugal	Isabel LAGINHA
Romania	Nicoleta CAROLE
	Simona DRAGOIU
Slovak Republic	Lucia MURÁNIOVÁ
	Anna SLIMÁKOVÁ
	Maria SKULTETYOVA (remote)
	Jana CHMELIKOVA (remote)
	Gabriela TOMKOVA (remote)
	Karol BLESAK (remote)
Slovenia	Tatjana HUMAR-JURIČ
	Marta PAVLIČ ČUK
Spain	Angela SANCHEZ CONDE
	David CANO
	Laura ZAMORA NAVAS
Sweden	Anneli RUDSTROEM
	Jonas FALCK
	Helena DORFH
	Jenny VIRDARSON

Candidate countries observers

Country	Name, surname
Montenegro	Tatjana MUJIČIĆ
	Ilija GOJOVIĆ
	Nevena BOGAVAC
Serbia	Bojana DORDEVIC
	Jelena GRUJIC
	Snezana MARKOVIC
Türkiye	Ahu ÇEKIM
	Nihat YAMAN
	Okan KUMCU

Third country observers

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Switzerland	Markus HOFMANN (remote)
	Olivier BLASER (remote)

Industry observers

Organisation	Name, surname
Cefic	Amaya JÁNOSI (remote)
Cefic	Camelia MIHAI
Fecc	Simina DREVE (remote)
ORO	Kevin HOBAN

Invited speakers

Organisation	Name, surname
EMA	Elfa EIHENBAUMA (remote)
	Efstratia VATZAKI (remote)
EFSA	Elisa SIMÉONI (remote)
	Charlotte DE VUYSSERE (remote)
	Elina CIEKURE (remote)

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	Evelyne FRAUMAN
	Francesco FACINCANI
	Gary WATKINS
	Malgorzata SZKLAREK
	Pedro ROSELLÓ VILARROIG
	Roxana BROASCA
	Viorica NAGHY
	Maciej BARANSKI
A1	Tiiu BRÄUTIGAM
B3	Jurgen RUOSS
A4	Anna DASZYNSKA
D4	Christina LOUKOU
C1	Anna-Liisa PIKKARAINEN
A3	Javier SANCHEZ
	Daniele APE
R3	Diego ALVAREZ
	Konstantinos ANAGNOSTAKIS
	Marko POPOVIC
	Taru NIEMINEN
	Viktoria EDES

[19] ECHA – organisation: https://echa.europa.eu/about-us/who-we-are/organisation

REACH Workshop

Opening by the Chair

Erwin ANNYS (ECHA), the Chair of HelpNet, opened the REACH Workshop by welcoming the representatives of the European Commission (DG GROW), national helpdesks (NHDs) and observers.

This document summarises the topics discussed[1] during the workshop (Annex I) and the follow-up action points (Annex II). The names of the participants attending the event are listed in Annex III to these minutes.

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission

Riccardo ZORGNO (European Commission, DG GROW) gave an update on the ongoing and the concluded REACH authorisations and restrictions, and on the state of play of the REACH revision, postponed to the last quarters of 2023.

In particular, he introduced the main agenda points of the upcoming REACH committee including, for authorisations, the Siemens-related applications (OPE_NPE) and decorative uses (chromium trioxide) and for restrictions, microplastics, skin sensitisers in textiles and lead in PVC. This was followed by an overview of the state of play of authorisations (adopted and ongoing decisions) and a state of play of the REACH revision, with indication to its delay (draft planned in Q4 2023). Concluding references were made to the upcoming advocate general opinion in case C-144/21 (European Parliament v European Commission).

Discussion

One correspondent asked whether it was possible to share more details on the specific titles and articles of REACH that will be affected by the revision. The Commission replied that it is difficult to assess which parts of the regulation will be changed, as the extent of the revision is still under discussion. Depending on the number of changes, there will either be a recast of the regulation, that would clearly take longer, or an amendment which will be limited to certain parts of the regulation; the latter would be the preferred way forward for the Commission. More information will be likely available towards the end of this year.

1.2 Update on ECHA registration activities

Amandine JOMIER (ECHA, Support and Enforcement Unit) presented an update on ECHA registration activities and highlighted current matters dealt with at the ECHA Helpdesk. Updates and information on the following topics were presented:

- Unclaimed NONS project and its impact on the ECHA chemical universe: Registration numbers for substances notified in accordance with Directive 67/548/EEC (NONS) cannot be claimed anymore, and all unclaimed NONS will be revoked.
- Only Representative (OR) declarations: The new requirement for ORs to identify the non-EU manufacturers they represent applying from 14 October 2022, ECHA collected information on the identity of non-EU manufacturers and the localisation of ORs in the EU.
- Questions related to sanctions: ECHA is receiving enquiries related to the war in Ukraine and how economic operators should comply with sanctions and restrictive measures.

[1] Disclaimer: Note that the text of the BPR, CLP and REACH regulations is the only authentic legal reference and that the summaries in this document do not constitute legal advice. For further advice, contact your national helpdesk.

- 'Substances in stock': There is an ongoing survey within the HelpNet to collect input on current practices and replies given to customers related to the placing on the market or use of substances 'not registered' anymore. The survey also includes questions related to the applicability of the exemption for recovered substances when existing registrations for substances being recovered are e.g. not valid anymore.
- Joint submission and lead role obligations: Regulatory and technical clarifications were shared related to the role, obligations and possible status of the lead registrant of a joint submission.
- Dissemination activities: The latest updates and upcoming developments were presented.

Discussion

One correspondent asked about the different elements to be provided by the OR in their declaration and what happens if they have not done it so far. ECHA clarified that the information includes the name and address of the non-EU manufacturer, an identification number of the company, if any, and the location of the manufacturing or formulating sites. The OR can also attach a letter of appointment or additional documentation. Companies that have not yet provided this information will be able to do so when logging into REACH-IT. It was also highlighted that from the end of October or beginning of November, registrants who declared in their IUCLID dossier that they are an OR will not be able to pass business rules in REACH-IT, unless they have provided the required information about the non-EU manufacturer.

The correspondent also asked ECHA to provide more information on the additional information that will be disseminated in relation to the SCIP database. The SCIP database improvements include better search functionalities, by adding search features by SVHC concern (carcinogenic, mutagenic, toxic to reproduction etc.) and a faster processing and publication of data. However, no change is foreseen in the SCIP data subject to dissemination and no additional information from SCIP notifications is expected to be published[2].

One NHD enquired whether there were any data on the percentage of existing joint submissions for the NONS and asked to clarify when the registrant needs to join a joint submission. ECHA replied that those figures were not available at the moment and clarified that for NONS, when a joint submission exists, the NONS registrant, like any other registrant, must join the joint submission to update their dossier. If no joint submission exists yet, they can decide to create one themselves. They are also able to update their dossier without creating one, but as soon as another registrant creates a joint submission, they will have to join it to be able to update their own registration.

Another correspondent mentioned that they were very interested with the information related to the dissemination platform and the upcoming possibility of bulk data downloads from REACH registrations in November 2022. After consulting with dissemination colleagues, ECHA explained that for the REACH datasets, there will be the possibility to download the full set of REACH registered substances and the full list of public registrants supplying registered substances. For the PIC dissemination, the whole PIC data will be downloadable.

One correspondent noted that their Member State (MS) had a lot of NONS. The NHD further asked whether revoked registrations are only unclaimed NONS, and whether it is possible to get further details on those. Since NONS cannot be claimed anymore, competent authorities still have the obligation to keep the information submitted to them under the previous directive. ECHA confirmed that indeed registrations to be revoked are unclaimed NONS and clarified that, for the files that national authorities need to keep, it would depend on the applicable retention period.

In addition, ECHA shared that the Agency is currently working on the IT implementation of a

[2] Post-meeting clarification.

project to make it possible for NONS notifiers to download their dossier from REACH-IT, like any other registrant. This should be possible from the beginning of 2023. The national helpdesk further asked more clarification on the OR figures and ECHA explained that from the total number of ORs that have declared the non-EU manufacturer, 35 % are located in their MS. Afterwards, ECHA also provided to that NHD the numbers of unclaimed NONS that were submitted to that MS.

One NHD noted that guidelines currently recommend that the list of suppliers is provided in the OR registration dossier and asked whether it now became an obligation. ECHA clarified that, although it is strongly recommended for registrants to provide that information, there is no legal obligation yet. It was also emphasised that the review of REACH Annex VI focused on the information to be provided by the OR related to the non-EU manufacturer, but nothing changed about the information on the operators importing under the OR scheme. The Chair also noted that in view of the REACH Revision, there are many discussions ongoing on the role and the obligations of ORs.

One correspondent asked some clarifications about the numbers of substances corresponding to the unclaimed NONS to be revoked. ECHA explained that the 4 738 registration numbers to be revoked correspond to 2 843 substances. Among those 2 843 substances, 1 500 substances had not been registered by any registrants in the EU and therefore, the ECHA 'chemical universe' will shrink by 1 500 substances.

1.3 Consideration of new information submitted in the dossier evaluation process including tonnage band change

William BROERE (ECHA, Legal Affairs Unit) presented an update on ECHA's new approach of taking into account new information during dossier evaluation, in particular with reference to tonnage downgrades in light of the recent Board of Appeal decision in joined cases A-006-2020 and A-007-2020. He gave an overview of the new administrative practice of ECHA, focusing in particular on what ECHA considers as 'new substantial information', how and what registrants need to communicate to ECHA so that such information is taken into account, and the difference between information submitted before and after the issuing of a final decision. He concluded with an outline of the topical helpdesk questions received on dossier evaluation updates.

Discussion

One NHD asked ECHA how the tonnage downgrade is calculated and William clarified that the registrants have to submit evidence that the substance that has been imported or manufactured over the calendar year preceding the tonnage band change is at the lower tonnage band.

1.4 Assessment of regulatory needs of a group of substances

Helena JÄRNSTRÖM (ECHA, Prioritisation Unit) provided an overview of the assessment of regulatory needs (ARN) of group of substances, with about ~100 colleagues contributing to this work. She explained how it fits in ECHA's Integrated Regulatory Strategy (IRS), how working on groups of substances speeds up the identification of chemicals that require regulatory actions and how stakeholders can engage. Links to more information on the topic as well as to the ARN list were also provided in the presentation.

ARNs is preparatory work to support REACH & CLP processes and authorities. It gives an early perspective on longer-term regulatory risk management as well as immediate actions needed for (groups of) substances. ARNs is the centre of the IRS – it does not replace anything but connects the existing processes & enables efficient selection of substances or groups of

substances that raise potential concern. Cooperation between ECHA, the European Commission and the Member States is the key to the efficient and effective implementation of the IRS.

Groups of substances in ARNs are primarily formed based on structural similarity, but also may take into consideration read-across and categories applied in the REACH registration dossiers. However, grouping for ARNs is different from the registrants' read-across or groups in regulatory processes. The main source for the ARN assessment is the information provided in the REACH registration dossiers. Chemistry, hazard and use experts assess the information and conclude on the next action as well as longer-term foreseen regulatory needs for the substances in the group to ensure their safe use. Member States are consulted before the publication of the ARN report on PACT. The publication of the ARN reports aims to increase the predictability and transparency on potential next actions on a group of substances. The focus is on the need versus no need for EU level regulatory risk management .

The presentation pointed out that ARN is not a formal process. To gain legal relevance, the substances assessed need to successfully pass the relevant regulatory processes under REACH and CLP. Also, to note is that ARN is an iterative process, which means that the suggested outcome (and report) may be revised when there is new information available. Meanwhile, industry is advised to be proactive, keep registrations up-to-date and follow the annual IRS report as well as the chemical Universe updates. Comments from stakeholders are appreciated and documented, however no direct interaction is foreseen. The comments may be considered in the next revision of the ARN report. ECHA's support page summarises Q&As on ARNs and a webinar addressing this topic was held on December 2021 for which the recording and Q&As are available on ECHA's web page as well.

1.5 Update on ECHA authorisation activities

Thierry NICOT (ECHA, Risk Management II Unit) presented an update on ECHA's authorisation activities. The presentation focused on the application for authorisation (AfA) activities the Agency is currently working on. The presentation gave an overview of the responsibilities following a granted authorisation and the actions for extending an authorisation beyond the review period, provided an update on the current status of AfAs and opinions, and informed about the current and future work on AfA opinion development and other authorisation activities.

It was highlighted that NHDs could raise awareness to downstream users (DUs) of hexavalent chromium (Cr(VI)) previously relying on an authorisation under Article 56(2) and not covered by the review report of their authorisation holder to start preparing their new authorisation applications as early as possible. NHDs could advise these DUs to:

- contact industry associations and search for suitable partners (companies, consultants) via the Partners' Service;
- contact their national enforcement authorities (NEAs) to proactively inform them about their situation;
- notify ECHA of their intention to submit an application and request to participate in a joint Teleconference Information Session (TIS) (first joint TIS on Cr(VI) uses to be held on 15 February 2023);
- contact the NHDs and ECHA (as applicable) if they have any questions while preparing or submitting their application.

It was underlined that ECHA is aware of the issue and will do its best to process the high peak of AfAs within the timelines allowed by the capacity of ECHA and the RAC & SEAC committees.

Discussion

A correspondent raised a question whether the use of decorative chrome plating is to be considered as an essential use or not in the context of AfA. ECHA highlighted that the criteria for the essentiality of a use have not yet been defined by the European Commission. ECHA underlined that the Decision for the use of functional chrome plating for decorative purposes (use 3, ID 0032-03) under the CTACSub authorisation application has not been issued by the European Commission up to date.

A correspondent asked about the status of the authorisation obligation for a mixture with an Annex XIV constituent which is linked to an ongoing discussion in HelpEx (HelpEx ID 17915) on More than One Constituent Substances (MOCS). ECHA provided the latest update on this topic underlining that, based on the REACH legal text, ECHA's understanding is that for a DU of a mixture containing an Annex XIV component above the thresholds of Article 56(6) for this mixture, an application for authorisation would be needed only if it can be concluded that the mixture has been formulated with the Annex XIV substance.

This fact can be, for example, confirmed if the safety data sheet (SDS) for the mixture includes the authorisation number for the use of the Annex XIV substance in the formulation of the mixture. In other words, an AfA should be considered for the use of the mixture only if an AfA is required for the formulation of the mixture. This situation may result in an unequal treatment of imported mixtures (where normally only information on the components of the mixture is available) compared to mixtures formulated in the EU. It is also noted that this approach is not consistent with the CLP approach for the classification of CMR substances and mixtures following a component-based approach, and the REACH Annex XIII approach for identifyinh PBT/vPvB substances. Moreover, this approach does not guarantee a high-level protection of environment and human health because it relies on the absence of information in the SDS as proof of the absence of a need for DUs to apply for authorisation although an Annex XIV component may be present in the mixture in a relevant concentration.

Within the current REACH legal framework, ECHA is unable to formulate an answer that:

- ensures a high protection goal for human health and the environment;
- is transparent and predictable for the supply chain;
- treats MOCS and mixtures in a similar way;
- is in line with how CLP considers MOCS and mixtures in the classification of CMRs; and
- does not lead to challenges identified for regulating substances in substances under the process of authorisation.

Furthermore, ECHA summarised the ongoing discussions and highlighted that this is part of the elements that need to be addressed under the revision of the legal text. As a result of the discussions, the Chair suggested to include an action point, where ECHA will share in writing with the NHDs the information on the MOCS considerations regarding the obligations arising from the presence of Annex XIV substances in mixtures.

Action point

Share in writing with NHDs the information on the MOCS considerations regarding the obligations arising from the presence of Annex XIV substances in mixtures.

1.6 Update on ECHA's restrictions activities

Augusto DI BASTIANO (ECHA, Risk Management I Unit) and Carmen KLAUSBRUCKNER (ECHA, Risk Management II Unit) presented an update on ECHA's restriction activities. They gave information on ongoing restrictions, introduced new restriction proposals, updated on other restriction-related activities performed in 2022, and informed about key issues in the restriction processes. The following were highlighted:

- Encourage stakeholders to engage as early as possible in the process, ideally soon after the intention is published.
- Promote the need for relevant and conclusive information. Indeed:
  - Scientific information should be supported by data, and be relevant to the scope of the restriction.
  - Information on substitution possibilities is crucial for SEAC to conclude on the impact of a restriction.
  - Robust information on risk and socio-economic impact (including costs) is needed for RAC and SEAC to formulate their opinions.
  - Information on analytical methods is relevant to conclude on enforceability.

Discussion

Two correspondents highlighted that it is a common challenge for the national helpdesks to reach the specific sectors or group of companies which are affected by the restriction entries. Furthermore, it was mentioned by a correspondent that there are common questions for new or upcoming restrictions in which the enquirers query if their substance is under the scope of a certain restriction entry.

ECHA underlined that information on the sectors impacted by the entry is typically available in the restriction dossier, and mentioned that a summary of most relevant uses (and impacted sectors) is also provided in the opinion development section of the restriction on ECHA's website. It was further noted that this question will be brought to the attention of the restriction team to verify if information on sector groups potentially affected may be provided as a summary in the restriction web page. Furthermore, ECHA emphasised that the final background documents prepared for each of the restriction entries define which substances are under the scope. These documents are publicly available on the ECHA website, however suggestions for improvement are always welcomed. As a result of the discussions, the Chair suggested to include this as action point.

Action point

Provide feedback on how ECHA can help to provide better support on restrictions with a broad scope to identify the sectors affected.

2. Topics proposed by HelpNet members and observers

2.1 What the German Helpdesk learnt since the nano-specific information requirements entered into force

Angelina GADERMANN from the German helpdesk (BauA)[3] gave a presentation on the learnings of the German Helpdesk since nano-specific information requirements entered into force, with reflections on the obligations for registrants and downstream users. The following elements were highlighted:

[3] Federal Institute of Occupational Safety and Health

- Nanoforms are not only manufactured or imported, but can also be produced. This aspect is of special relevance when it comes to downstream users, and it is not covered under Article 6. Substance can have different forms but a form is a characteriser, not an identifier, and the production of a new form does not change the substance identity. Therefore, the production of a new form is not manufacturing, and no registration obligations should apply.

- For manufacturers and importers of a substance, the quantities to be considered when registering the substance is the sum of the quantities of all forms of the substance.

The German national helpdesk reminded what the information requirements for dossiers containing nanoforms are, and the information that needs to be included in the safety data sheet (SDS) for substances and mixtures. They highlighted the different situations that can be seen for substances and mixtures, depending on their registration statuses, and the different levels of information that will be included in the SDS.

In addition, to share their experience and some views on existing shortcomings or unclarities in the legislation as regards to the registration obligations related to nanoforms, the German national helpdesk made some concrete proposals to clarify those situations and suggested adaptations to the legal text. They also highlighted the need for further guidance and Q&As.

3. Break-out groups session

Eduardo BARRETO TEJERA (ECHA, Support and Enforcement Unit) explained the organisation of the break-out groups' session to participants. The five topics listed were introduced to the plenary by the respective national helpdesks who suggested them. Participants were then divided into small groups of six to eight participants to discuss the different topics.

After the discussions, participants reconvened in the main meeting room to present the outcome of the exchanges. The topics discussed were:

- Topic 1: Issues faced by ORs of non-EU manufacturers who no longer exist.
- Topic 2: Registration, waste and recovered substances – status of by-products.
- Topic 3: Information obligation – REACH Article 33, practical problems, uncertainties, and possible misunderstandings in the legal text.
- Topic 4: How to help article suppliers identify if they are affected by an Annex XVII entry or if their articles contain an SVHC.
- Topic 5: Understanding the intricacies of the training requirement (case of the diisocyanates restriction).

Action point

Share the Forum discussion on Entry 74 (diisocyanates) after the Forum meeting in November with HelpNet colleagues.

Closing of the REACH Workshop

The Chair listed the action points (Annex II) resulting from the REACH Workshop and thanked all participants for their active participation and contribution to the discussions.

Annex I – Agenda of the REACH Workshop

REACH Workshop (9:30-16:45)

Opening by the Chair

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission (DG GROW Riccardo ZORGNO)

1.2 Update on ECHA registration activities (ECHA, Amandine JOMIER)

1.3 Consideration of new information submitted in the dossier evaluation process including tonnage band change (ECHA, William BROERE)

1.4 Assessment of regulatory needs of a group of substances (ECHA, Helena JÄRNSTRÖM)

1.5 Update on ECHA authorisation activities (ECHA, Thierry NICOT)

1.6 Update on ECHA restrictions activities (ECHA, Augusto DI BASTIANO)

2. Topics proposed by HelpNet members and observers

2.1 What the German Helpdesk learnt since the nano-specific information requirements entered into force (Germany, Angelina GADERMANN)

3. Break-out groups – Discussion on selected topics

Introduction of the topics by moderators

Discussion in groups

Reporting back to the plenary

Conclusions of the day

Closing the REACH Workshop

Annex II - Action points

No.	Action	Agenda item	Who	Status
1.	Share in writing with NHDs the information on the More than One Constituent Substances (MOCS) considerations regarding the obligations arising from the presence of Annex XIV substances in mixtures.	1.5	ECHA	Closed
2.	Provide feedback on how ECHA can help providing better support on restrictions with broad scope to identify sectors affected.	1.6	ECHA	Ongoing
3.	Share with the HelpNet colleagues the Forum discussion on Entry 74 (diisocyanates) after the Forum meeting in November.	3.1	ECHA	Ongoing

Annex III - List of participants

Country	Name
Austria	Barbara WETZER
	Stephanie CASTAN (remote)
Belgium	Daphné HOYAUX (remote)
Bulgaria	Zvezdelina PETROVA
Cyprus	Maria ORPHANOU
Croatia	Tajana KOVACEVIC
Czech Republic	Jarmila SLADKOVA (remote)
Denmark	Maria THESTRUP JENSEN
	Toke THOMSEN (remote)
Estonia	Anna AMELKINA
Finland	Sari TUHKUNEN
France	Gaëlle DUFFORT
	Nathalie HAYAUD
Germany	Angelina GADERMANN
	Heinz BUELTER (remote)
Greece	Eleni FOUFA (remote)
Hungary	Tamas KOVAC
Ireland	Majella COSGRAVE
Ireland	Margarete HOULIHAN (remote)
Italy	Francesca CARFI
	Sabrina MORO IACOPINI (remote)
Latvia	Sandra MATISA
Lithuania	Beata VOLUJEVIC
Luxembourg	Laurène CHOCHOIS
Malta	Nathanel ELLUL
	Antonino MAZZONELLO(remote)
Netherlands	Peter VAN IERSEL (remote)
Norway	Cecile BLOM
	Abdulqadir Mohamad SULEIMAN
Poland	Krzysztof DOMAŃSKI (remote)
	Monika WASIAK-GROMEK (remote)
Portugal	Isabel LAGINHA
Romania	Nicoleta CAROLE
Slovakia	Anna SLIMAKOVA
	Karol BLESAK (remote)
Slovenia	Simona FAJFAR (remote)
Spain	Laura ZAMORA NAVAS
Sweden	Helena DORFH
	Jenny VIRDARSON

European Commission

DG	Name, surname
DG GROW	Riccardo ZORGNO

Candidate countries observers

Country	Name, surname
Montenegro	Tatjana MUJICIC
Montenegro	Nevena BOGAVAC
Montenegro	Ilija GOJOVIĆ
Serbia	Bojana DORDEVIC
Serbia	Jelena GRUJIC
Serbia	Snezana MARKOVIC
Türkiye	Ahu ÇEKIM
Türkiye	Okan KUMCU
Türkiye	Nihat YAMAN

Industry observers

Organisation	Name, surname
Cefic	Amaya JANOSI (remote)
EDANA	Luminița BARBU (remote)
FECC	Simina DREVE (remote)
ORO	Kevin HOBAN

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[4] ECHA – organisation: https://echa.europa.eu/about-us/who-we-are/organisation

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	Maciej BARANSKI
	Malgorzata SZKLAREK
	Pedro ROSELLÓ VILLAROIG
	Roxana BROASCA
	Viorica NAGHY
A4	Alexis QUINTANA-SAINZ
	Maria Jose BELMONTE SANCHEZ
B1	Janne KILPINEN
B3	Helena JÄRNSTRÖM
B4	Telmo Jorge VIEIRA PRAZERES
D3	Augusto DI BASTIANO
D4	Christina LOUKOU
D4	Thierry NICOT
E2	Fausto COMANDÈ
	William BROERE
R3	Viktoria EDES

CLP Workshop

Opening by the Chair

The Chair, Erwin ANNYS (ECHA) welcomed the 33 participants of the workshop, present in person, and the 25 correspondents who followed it remotely. He pointed out that up to 17 ECHA staff members would participate (four of them remotely) which highlighted the variety and importance of the topics to be discussed. The Chair explained the meaning of the name of the meeting room, Voima, and went through the house rules. The Chair also presented the draft agenda, which was approved without comments. Afterwards, he reported on the list of action points, out of which only two were pending. They would be closed by the presentation from the European Commission (COM).

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission

Jérémy PINTE (European Commission, DG GROW), representing the CLP team, introduced Svetlana SKRYNIKOVA as the replacement of Anna SCHUSTER. His presentation covered the process and timelines of the CLP revision, an overview of the delegated act with new hazard classes and other regulatory instruments.

Jérémy PINTE opened the first part of his presentation by explaining how the current legislative proposals had come to life. In particular, the evaluation of existing legislation and stakeholder input led to 17 policy measures bundled into three independent policy options that resulted in the CLP revision package. This would be an ordinary legislative procedure involving both co-legislators (the European Parliament and the European Council) and a Commission delegated act. The Impact Assessment, to be published together with the legal acts, would cover topics to be implemented by both legal instruments. COM was at that moment refining the Impact Assessment and replying to the comments received. They were still positive that the Delegated Act and the proposal for the Ordinary Legislative Procedure would be adopted by the Commissioners on the same day in 2022.

The second part of the presentation focused on the new hazard classes included in the Delegated Act, starting with the Endocrine Disruptors (ED). There would be separate classes for human health and for the environment. In Category I, the substance would need to meet three criteria at the same time. In case of doubt about the relevance of the adverse effect, it would fall into Category II. The hazard statements would be indicated as EUH-statements. There could be no pictogram at present as this might create interference with the use of the existing pictograms covering current hazards in the UN Globally Harmonised System (GHS) level and impact international trade. If new pictograms are created for the new hazard classes, they should be agreed at UNGHS first so that they can apply across the UNGHS members. The COM was taking steps to address this issue.

The persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) hazards shared a lot with PBT/vPvB, and are of a high level of concern. The Commission considered the criteria that was already present in several pieces of legislation, but the assessment of P should be harmonised. The criteria for these hazards were applicable only to organic chemicals. Mobility (M) would be measured only with one parameter: the soil adsorption coefficient. For coefficients ≤ 3, the substance would be mobile, and for coefficients ≤ 2 the substance would be very mobile. Regarding communication, again EUH-statements would be in place with no pictogram, as there were no global criteria yet. Also, no new precautionary statements. The Commission had already planned to update the guidance documents both for Industry and the Competent Authorities.

Considering the ED and mobility, the Commission acknowledged that while there was already guidance, it was spread over several documents and therefore not very user friendly.

Regarding the Impact Assessment, it split the costs from industry into compulsory (need to reclassify and relabel) and voluntary (reformulation of mixtures to avoid classification). The social impact had been estimated based on benefits over several generations and considering savings in healthcare. For example, reduction of the exposure to ED could mean EUR 300 million in savings per year after two generations. The environmental impact, estimated in around EUR 40 million, was largely based on the maintenance of biodiversity.

The work at GHS level to include the six new hazard classes would be spread over the next two years. This would be combined with work at the OECD level. To achieve this, the Commission would need input and expertise from Member States, agencies and industry.

The Commission wanted to strengthen and speed up the harmonised classification system. They wanted to provide more clear rules for classifying more than one component substances (MOCS), which meant applying the mixture classification rules, with some adaptations. The bridging principles were also being reviewed, taking into account the input provided by the working group on that topic of the Forum for enforcement. The Commission also wanted to make the mandatory requirement to update self-classificaiton within six months of receiving relevant information.

Moving to labelling matters, the Commission outlined that the CLP revision should bring more user-friendly labels by increasing readability, allowing digital labels for certain supplementary information and having a broader use of fold-out labels, in particular, to cover the issue of multi-language labels. Furthermore, the labelling derogations could be extended when no safety issue would be at stake.

Finally, the Commission wanted to clarify provisions of Article 45, introducing targeted notification obligations to poison centres for relabellers, rebranders and distributors. The aim was to prevent the loss of information when mixtures are transferred from one MS, where a notification is in place, to another, where there is no notification.

Discussion

One CLP correspondent asked three questions, the first one being to confirm that the idea that no substance or mixture could be placed on the market unless a supplier ensured conformity with CLP would refer to PCN obligations as well and not only to online sales in general. The Commission confirmed that this was their intention.

The second question was to clarify the message about speeding up the initiation of harmonised classification proposals, and to know to whom it was addressed. The Commission replied that CLP is the cornerstone of the "one substance, one hazard assessment" principle. In the future, revised downstream legislation (cosmetics, or toys, for example) would identify hazards according to CLP, and in particular they would be based on the harmonised classification. Consequently, the harmonised classification procedure needs to be a high-output one. To that end, the harmonised classification dossiers could be developed for groups of substances (until now the maximum had been two or three substances per dossier). A second measure would be to give the Commission powers to initiate a dossier and ask ECHA to prepare it. The current system, where the Commission uses a contractor and afterwards looks for a supporting MS was considered to be inefficient.

The third question was about the idea that the new hazard classes would be applied across all legislation: how would the Commission handle the situation where REACH, biocides and

pesticides legislation will have at some point differing criteria about endocrine disruption to that of CLP? The Commission did not see a clash of criteria amongst the different pieces of downstream legislation referring to CLP but acknowledged that at some point those pieces of legislation would need to be reviewed and their own criteria should be removed to make a direct reference to the CLP.

An ECHA staff member asked for clarification about the trigger to update the self-classification six months after new information has become available. The Commission explained that the trigger was indeed when a new piece of information becomes available to a company, the clock would start ticking then. This piece of information could eventually be a new harmonised classification. The Commission also considered that this clear rule would give certainty to inspectors when checking the self-classifications.

One industry observer asked about the background to the newly proposed labelling derogation to writing instruments, after so many years of discussions. The Commission explained that the idea was to simplify provisions that otherwise were too complex. The Impact Assessment had shown that providing certain labelling derogations to chemicals supplied in very small packaging, such as part of the writing instruments, would lower the burden for business while not triggering significant adverse impacts on human health and the environment.

Action point

Provide the link to the extract of the impact assessment study in S-CIRCABC.
Share with the CLP correspondents the list of nicotine-like products that has been sent to the Commission.

1.2 Operation of PCN in numbers. Available support material

Pedro ROSELLÓ VILARROIG (ECHA, Support and Enforcement Unit) provided an update on the status of the poison centre notification (PCN) activity from ECHA's point of view. This included a refresher on the ways in which duty holders can submit notifications as well as some figures on the submissions handled by ECHA. He also provided the most current questions received, with their reasoning and ways forward. This information was complemented with the list of available support material, highlighting which was translated into all EU official languages. The presentation ended pointing out the maintenance mode in which the IT tools were at the moment, and the features of the October 2022 release.

Discussion

One CLP correspondent asked to clarify the number of notifications to MSs and the number of submissions, as they did not sum up. ECHA explained that a single submission could include several notifications to different MSs (multimarket submissions). Because of this, the overall number of submissions was well below the sum of the number of notifications per MS. The CLP correspondent also wanted to know about the absolute number of companies using the system-to-system (S2S) route. The Secretariat committed to provide a number on users of the S2S protocol. ECHA explained that, in any case, these companies had large portfolios and therefore were fully benefiting from this option.

Another CLP correspondent expressed their interest to know when ECHA was forwarding customers to contact the NHDs. The Secretariat agreed to consult again the HelpNet on their individual interest to be blind copied when ECHA would forward a customer. The CLP correspondent also thanked ECHA for including in the PCN microsite information about the telephone number to be included in Section 1.4 of the safety data sheet (SDS), information that is not always properly understood. The last question from the CLP correspondent was about the possible communication module in the ECHA submission portal. ECHA informed that this topic would be tackled in the PCN Stakeholders' meeting taking place on the 3 November.

Action points

Provide the number of companies submitting poison centre notifications through the system-to-system (S2S) integration functionality.

Ask again from the CLP correspondents, which of them would like to be in blind copy when ECHA redirects customers to their NHD.

2. Topics proposed by HelpNet members and observers

2.1 Classification of lead containing mixtures/alloys and HelpEx 18507

Dr Anja HACKMANN (BAuA[1], German helpdesk) outlined to the audience the question HelpEx 18507, originated by Bulgaria, based on the current entries of Lead in Annex VI to CLP. She also mentioned the intention to amend this entry in the 21st ATP. The heart of the matter was whether the particle size mentioned in the entry referred only to the lead particles as such or also to the particles containing lead. Recent discussions in CARACAL only touched on the issue at the periphery and thus did not lead to a solution. The issue could reoccur in the upcoming CLH for silver, which would have three entries, one per form: massive, powder and nano.

The presentation ended with a poll about how the other NHDs were replying to the question about classifying alloy powders containing lead. The results were:

- Refer to entry on massive lead: 2
- Refer to entry on powder lead: 6
- Answer is unclear and discussed in HelpNet currently: 11

Discussion

The representative of the Commission mentioned that they would change the approach of the entry in Annex VI and would report back to CARACAL, probably on 17 November. Their intention was to rework the environmental side of the entry. They welcomed the input from HelpNet and would be interested in having input too about the matter of classifying alloys in general. They also mentioned that proposals for other metals were coming forward: copper, silver and others.

ECHA acknowledged that the entry was not so clear. Moreover, it only made sense if it referred to the alloy and not only to lead particles.

There was a general agreement that alloys are complicated mixtures to be classified, and that discussing on the consideration as "special mixtures" under REACH (as CLP does not include this concept) was not helpful. The need for further guidance was identified. ECHA reminded about previous attempts (CASG on bioelution) to provide such guidance, but the approach taken was not supported by MSs.

The Chair suggested to discuss the matter in a video conference and share experiences, hoping to stimulate and reopen the discussion. All parties would need to reflect on it beforehand, in any case.

Action point

Follow-up the discussion on the classification of alloys, possibly in a future video conference.

[1] Federal Institute of Occupational Safety and Health

3. Training on CLP classification

Introduction

Outi TUNNELA (ECHA, Exposure and supply chain Unit) introduced the exercise and linked it to the training she provided online a year ago. Having now the opportunity to provide a similar case live would make it more effective and would allow for a better discussion on both the partly clear-cut answers, as well as on more general issues about classification needs and the quality of the safety data sheet information. Outi TUNNELA then went through the material which had been circulated in advance to the participants.

For working on the exercise, the participants were grouped in trios, taking into account the distribution of those who had participated the previous year.

Discussions

Outi TUNNELA summarised some of the points discussed, committing to share afterwards an updated 'answers' presentation with the participants. The points raised included the reminder that classification of a mixture has to be done based on the upper values of the concentration ranges provided. Further, one of the components was quartz present at >50 %, which opened the discussion whether the mixture was actually a solid (a paste) and therefore inhalation exposure should have been considered. A main conclusion in the discussion on the content of SDS Section 3.2 was that the substances indicated therein must include the classification as appropriately derived in accordance with CLP. Considerations of exposure (based on form or physical state) cannot be taken into account in this section, even if they might affect the classification and labelling of the final mixture. Another point to note with the mixture in question was that the SDS stated "Restricted for professional users", though as explained by the trainer, the product was freely available online. All-in-all, in most part, the classification of the mixture seemed correct – where there was adequate information provided, but still a part remained unclear due to insufficient or contradicting information given in the safety data sheet (SDS).

Closing of the CLP Workshop

The Chair listed the action points of the workshop. He thanked the presenters for their contributions and all participants for the interesting discussions, hoping they had both learnt and enjoyed the classification training. He invited the participants to reply to the satisfaction survey, which would be sent after the meeting. The exact dates of the next CLP workshop would be announced later, after concluding on the vote to have the Steering Group meeting in the first half of the year. The CLP Workshop was then closed.

Annex I – Agenda of the CLP Workshop

Opening by the Chair

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission (DG GROW, Jérémy PINTE)

1.2 Operation of PCN in numbers. Available support material (ECHA, Pedro ROSELLÓ VILARROIG)

2. Topics proposed by HelpNet members and observers

2.1 Classification of lead-containing mixtures/alloys and HelpEx 18507 (Germany, Anja HACKMANN)

3. Training on CLP classification

Introduction (ECHA, Outi TUNNELA)

3.1 Exercise

Discussions

Conclusions of the day

Closing the CLP Workshop

Annex II - Action points

No.	Action	Agenda item	Who	Status
1.	Provide the link to the impact assessment study in S-CIRCABC.	1.1	Commission	Closed
2.	Share with the CLP correspondents the list of nicotine-like products that has been sent to the Commission (follow-up of previous action point).	1.1	ECHA	Closed
3.	Provide the number of companies submitting poison centre notifications through the system-to-system (S2S) integration functionality.	1.2	ECHA	Closed
4.	Ask again the CLP correspondents, who from them would like to be in BCC when ECHA redirects customers to their NHD.	1.2	ECHA	Ongoing
5.	Follow-up the discussion on the classification of alloys, possibly in a future video conference.	2.1	ECHA/NHD	Ongoing

Annex III – Results of the polls

Agenda item 2.1 - Classification of lead-containing mixtures/alloys and HelpEx 18507

What do you answer to a company on the question about how to classiy lead containing alloy powder?	
A. Refer to entry on massive lead.	2
B. Refer to entry on powder lead.	6
C. Answer is unclear and discussed in HelpNet currently.	11

Annex IV - List of participants

Country	Name, surname
Austria	Barbara WETZER
	Stephanie CASTAN (remote)
Belgium	Kristof CLAES
Croatia	Zdravko LOVRIĆ
Cyprus	Maria PALEOMILITOU
Estonia	Aigi LAHE
Finland	Elina BRUSILA (remote)
France	Gaëlle DUFFORT
	Nathalie HAYAUD
Germany	Anja HACKMANN
	Claudia BECKER (remote)
	Nicolaj HEUER (remote)
	Nirtharsan PARANSOTHY (remote)
Hungary	Eszter GÁBOR
Iceland	Fifa KONRADSDOTTIR (remote)
Ireland	Majella COSGRAVE
	Margarete HOULIHAN (remote)
Italy	Silvia ALIVERNINI
	Sonia D'ILIO (remote)
	Maria ALESSANDRELLI (remote)
Latvia	Agne JANONYTE (remote)
	Sandra MATISA
Lithuania	Jurgita BALČIŪNIENĖ
Luxembourg	Laurène CHOCHOIS
Malta	Nathanael ELLUL
Netherlands	Femke AFFOURTIT (remote)
	Jelle VRIEND (remote)
	Peter van IERSEL (remote)
Norway	Elena KLÅPBAKKEN DRØNEN
	Abdulqadir Mohamad SULEIMAN
Poland	Krzysztof DOMAŃSKI (remote)
Poland	Monika WASIAK-GROMEK (remote)
Portugal	Isabel LAGINHA

Country	Name, surname
Romania	Nicoleta CAROLE
Slovakia	Gabriela TOMKOVA (remote)
	Lucia MURANIOVA
Slovenia	Tatjana HUMAR JURIČ
Spain	Angela SANCHEZ CONDE
	Laura ZAMORA NAVAS
Sweden	Jonas FALCK
	Susanna NORRTHON RISBERG (remote)

European Commission

DG GROW	Jérémy PINTE (remote)
DG GROW	Svetlana SKRYNIKOVA (remote)

Candidate countries observers

Country	Name, surname
Montenegro	Ilija GOJOVIĆ
Serbia	Bojana DORDEVIC
	Snezana MARKOVIC
Türkiye	Ahu ÇEKIM
	Nihat YAMAN

Third Country observers

Country	Name, surname
Switzerland	Markus HOFMANN (remote)

Industry observers

Organisation	Name, surname
Cefic	Liisi DE BACKER (remote)
Fecc	Simina DREVE (remote)
ORO	Kevin HOBAN

ECHA staff

Unit[2]	**Name, surname**
Support and Enforcement	Amandine JOMIER
	Anita TUOMAINEN
	Eduardo BARRETO TEJERA
	Erwin ANNYS
	Francesco FACINCANI
	Malgorzata SZKLAREK
	Pedro ROSELLÓ VILLAROIG
	Viorica NAGHY
Submission and processing	Daniele APE
	Heidi RASIKARI
	Javier SANCHEZ SAEZ
Classification	Anna-Liisa PIKKARAINEN
Exposure and supply chain	Outi TUNNELA
Corporate services	Daniel NYGARD

[2] ECHA – organisation: https://echa.europa.eu/about-us/who-we-are/organisation

BPR Workshop

Opening by the Chair

Erwin ANNYS (ECHA), the Chair of HelpNet, opened the BPR Workshop by welcoming the representative of the European Commission (DG SANTE[1]), national helpdesks (NHDs) and observers.

This document summarises the topics discussed during the workshop (Annex I) and the follow-up action points (Annex II). The names of the participants attending the event are listed in Annex III to these minutes.

1. Updates from the European Commission and ECHA

1.1 Updates from the European Commission

Ligia NEGULICI (European Commission, DG SANTE) gave an update on the new legislative, political and regulatory developments on BPR topics, as follows:

- The Chemical Strategy for Sustainability – the impact on biocides deriving from the REACH and CLP revisions was discussed, the 'one substance, one assessment' initiative, the cumulative risk assessment and the possible PIC-related export ban.
- *In situ* products – it was clarified that Article 19(4) applies to all biocidal products including case-type 4 *in situ* products, which are generated *in situ* from precursors non-marketed for biocidal purposes. Concerning *in situ* generated active substances, CLH proposals should be submitted also for these active substances and they should refer to the pure substance.
- Review Programme delays – the Commission will offer financial support to MSs, which could be used for the work on evaluation of substances in the Review Programme, in the form of a grant.
- Post authorisation conditions – it was clarified that physical hazards and respective characteristics which affect product classification and labelling cannot be addressed by post-authorisation conditions, which are only possible for those phys-chem properties that would not affect Article 19(1) conditions and efficacy/risk assessment.
- New Q&As on the simplified authorisation procedure – since no specific renewal procedure is foreseen for renewal, an authorisation application needs to be submitted 550 days before the expiry date of the initial authorisation, to continue to keep the product on the market. It was then reminded that products containing Annex I active substances can be authorised in any product type.
- Approvals of skin sensitisers used in in-can preservatives, such as isothiazolinones (ISZs) – in detergents, the use of PPE is not recommended, but ISZs could be replaced by alternatives that do not exceed the specific concentration limit (SCL). In paints, there is a lack of alternatives, hence gloves can be recommended for use. Discussions on the topic are still on-going.

[1] Directorate-General for Health and Food Safety

- Wording of P-statements in the SPC - final wording of P-statements has to be established by the evaluating authority in the final SPC, taking into account the result of the risk assessment. P-statements and RMMs need to complement each-other.

Discussion

ECHA asked whether there are indications that sufficient MSs will submit an application to benefit from the financial support offered by the Commission for finalising the evaluation of substances in the Review Programme.

The Commission clarified that some MSs may not be able to do so, due to their national specificities, which would not allow them to go towards a full cost recovery fee system. In fact, one of the conditions for applying for the grant is that MSs commit to put in place a fee system that would allow a full cost recovery.

However, the Commission considers the financial grant as a small step forward for supporting MSs. The activities included in ECHA's active substance action plan also represent an important means of support.

Concerning skin sensitiser in-can preservatives, a HelpNet observer noted that the use of gloves was recommended for paints, but not for detergents and asked clarification on the way and form that gloves need to be provided. The Commission indicated that there is no clear position yet, as discussions on this topic are still on-going.

A HelpNet member asked whether Article 19(4) could be applied to *in situ* products placed on the market during the transitional period. The Commission explained that Article 19(4) applies to products authorised under the BPR and that the regulation of products placed on the market during transitional measures remains at the discretion of MSs and their national laws.

1.2 Updates from ECHA

Claudio PUTZU (ECHA, Biocidal Active Substances Unit) gave an overview of the role and division of tasks between the two biocides units (as requested in the survey by one NHD), and informed about the latest developments especially on the guidance updates ('Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C)', 'EFSA/ECHA guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water', 'Recommendation of the BPC Working Groups – *In situ* generated active substances – Risk assessment and implications on data requirements for active substances generated *in situ* and their precursors').

The speaker highlighted the recent changes on the ECHA website, such as the creation of a new subpage dedicated to the activities of the Coordination Group (the CG), the publication by ECHA of its opinions on the classification on changes and the upcoming publication of a list of MSs that allow the placing on their market of articles treated with creosote.

Discussion

ECHA acknowledged the importance of the CG web page, which offers easy access to all agreed documents. There was a question about the reasons for the publication of it, e.g. if it was triggered by some specific discussions in different fora. The speaker explained that the aim was to clarify the role of the CG, which is especially important for new parties/stakeholders entering

the biocidal market. The page increases transparency and supports cooperation between all stakeholders – the CG, ECHA and the applicants. The Commission also appreciated the dedicated web page and stressed the link of the CG discussions to the CA meetings.

Cefic invited the speaker to provide more clarification on ECHA's activities within 'one substance, one assessment'. Claudio PUTZU explained that there are many activities falling within the scope of this initiative, such as regular meetings between ECHA and EFSA related to the assessment of specific substances, cooperation for the implementation of IUCLID for pesticides, collaboration on the guidance development of common interest like PUTZUGuidance to assess the risk to bees and other non-target arthropod pollinators from the use of biocides', or 'EFSA/ECHA guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water'. This cooperation is also highly appreciated by the Commission as it improves the coherence among the agencies' work. Cefic highlighted the discrepancies between the exposure and use conditions between biocides and pesticides and the fact that this should be taken into account when working on common guidance. Claudio PUTZU noted the comment and assured that any cooperation between ECHA and EFSA considers the commonalities and the differences between both groups of products.

One of the observers was interested to know if there is an update of the efficacy guidance related to requirements for air disinfection. ECHA will check if this is covered within the ongoing revision of PT1-PT5 with the efficacy working group.

Action point

Check with the Working Group - Efficacy whether there is a guidance update related to efficacy requirements for air disinfection.

1.3 Enforcement activities of the Forum BPR Subgroup

Nicola TECCE (ECHA) from the Support and Enforcement Unit presented the information related to two enforcement projects and the follow-up actions of:

- REF-8 on the online sale of biocidal products, including the evaluation of online advertisements.
- Ongoing BEF–2 on biocidal products containing approved and not approved substances.

The speaker highlighted the importance of BEF-2 that is expected to show the whole picture of the biocides market due to coverage of products authorised both under the BPR and national laws and the involvement of almost all the actors in the supply chain making available biocidal products. BEF-2 includes different modules (e.g. on Article 95, advertisement, labelling and packing) but also a new module on chemical analysis that was recommended by BEF-1. Nicola TECCE offered to share the summary of the BEF-2 Workshop (June 2022) with HelpNet members.

Furthermore, Nicola TECCE discussed the results of REF-8 and the follow-up workshop with ASOs and the Commission, that took place in May 2022. He explained that the high level of incompliance (77 %) reported may be linked to the fact that the project targeted areas of allegedly incompliant products, where incompliance was expected to be found. He also agreed to share with HelpNet members the 'Guide for inspectors on control of online sales', resulting

from the REF-8 recommendations.

For the upcoming events, the speaker invited the participants to the training on 2 December – 'CLP for biocides, *in situ* generation systems and BPR borderline issues'. The invitation to the event, together with the 'BPRS Manual of Conclusions' will be distributed by the HelpNet Secretariat. The speaker highlighted that the 'Manual of conclusion' is not legally binding, but it aims to harmonise the interpretation and the enforcement of the BPR provisions.

Discussion

Cefic asked about the operational phase of BEF-2. Nicola TECCE explained the practice as regards to enforcement projects. The first year of the project consists of a planning phase, followed by an operational phase, which is when the inspections take place. For BEF-2, on-site inspections and desktop inspections are already ongoing. They are expected to be finalised in December 2022. The results of the inspections are to be gathered and sent to ECHA by national coordinators. This feedback is expected in January 2023 and the reporting phase for BEF-2 is planned for 2023.

The Chair asked if based on previous enforcement projects, there are any visible improvements regarding compliance with the BPR provisions. Nicola replied that it is too early to identify some patterns in the data collected by the BPRS during the last three years of activities. Overall the high level of incompliance observed (especially in relation to the online sales) may be linked to the fact that the biocidal market is defragmented, and many companies operating are SMEs that are quite often unaware of their obligations under the BPR. BEF-2 will provide a better overview on the EU market for biocides.

Action points

To share with the HelpNet members (BPR confidential folder in S-CIRCABC):
- The summary of the BEF-2 Workshop (June 2022);
- The 'Guide for inspectors on control of online sales' resulting from the REF-8 recommendations; and
- The 'BPRS Manual of Conclusions'.

1.4 Legal update

Camilla BUCHANAN (ECHA, Legal Affair Unit) gave an update on legal developments relating to the BPR, in particular:

- Data protection periods under Article 95(5) of the BPR – all data protection will end on 31 December 2025 for review programme active substances not approved before 1 September 2013. The Commission has confirmed that the expiry date will not be prolonged.
- Change in the role and involvement of applicants in the opinion forming process – to create efficiencies, applicants will no longer be allowed to comment in the first round of the peer review phase. Applicants' comments on the draft assessment report need to be submitted to the evaluating competent authority (eCA) before the report is submitted to ECHA. The eCA will compile the comments and the replies to the comments, and share

them with other eCAs during the peer review. The applicants will have an opportunity to attend the working groups as observers and comment on the amended assessment report before the BPC.
- 'One substance, one assessment' objective – the Commission is working on a proposal for a new regulation on the evaluation of chemicals to streamline scientific assessments and to improve alignment across regulations. This will allow the sharing and use of data among agencies and across different pieces of legislation e.g. REACH and Plant Protection Product data can be used for the BPR and vice versa.
- Judgments – PHMB appeal and silver cases were discussed.

Discussion

Cefic expressed its concerns about the lack of prolongation of the data protection expiry date dictated by Article 95(5) of the BPR. It was pointed out that the evaluation of substances in the Review Programme is not yet finalised, the guidance documents are changing continuously impacting the generation of data. ECHA's Legal Affairs Unit (LAU) echoed the concerns and suggested to raise them with the Commission. In turn, the Commission welcomed industry to come forward and bring up their views on the matter.

Additionally, both the Commission and Cefic asked about the reasons that triggered the change in the procedure related to the involvement of applicants in the opinion forming process. Cefic highlighted that applicants know their applications best and can help to address issues, hence, it would not be beneficial to exclude them from participating in the peer review. It was also emphasised that the new procedure would bring a discrepancy between the way UA and NA/MRs are handled. Camilla BUCHANAN explained that the involvement of the applicants in the opinion forming process represented a bottleneck that generated delays and that there was a need to bring efficiencies to the process. Cefic argued that the participation of the applicant in the peer-review could not be regarded as a major cause of delay in the approval process. It was then noted that the procedure could further be amended if it proved not to work well in the future.

1.5 Hot topics from the ECHA Helpdesk

Malgorzata SZKLAREK (ECHA, Support and Enforcement Unit) presented the hot topics and trends in regulatory questions received by the ECHA helpdesk. The estimated number of questions for 2022 is expected to be slightly lower than the last two years in which there was a increase in questions due to the COVID-19 pandemic.

The projection for 2022 indicates that the total amount of questions is returning to the levels observed in the pre-COVID years. As regards to the most popular topics, the biggest change has occurred in two categories: active substance approval and Article 95. This may be linked to the relatively slow progress in the Review Programme – as less substances are being approved and less dossiers are being validated before they become eligible for the Article 95 list. The speaker shared specific examples of questions received by ECHA related to active chlorine releasers and Annex I substances and highlighted AS/PTs of most interest.

Later Malgorzata SZKLAREK discussed the latest developments in the field of Q&As (new search tool, revision of the BPR Q&As finalised in 2022, development of two new Q&As) and announced

the upcoming change of the structure of BPR Q&As – which will combine both regulatory and technical questions under one topic.

Discussion

One of the NHDs referred to the presented example related to technical equivalence, where the device for the production of the active chlorine releaser is installed in another country. The NHD asked whether technical equivalence would be needed if the device is installed in different location but within the same country. ECHA confirmed that this would be also considered as a change in the manufacturing location and technical equivalence would also be required to be proven.

2. Topics proposed by national helpdesks

2.1 An overview of Poison Centre Notification obligations and biocidal products

Heidi RASIKARI (ECHA, Submission and Processing Unit) gave a general overview about poison centre notification obligations, covering also biocidal products. She explained that the obligation stems from Article 45 of CLP and noted the practical challenges related to its implementation, given that MSs have different requirements and formats for collecting the information. She highlighted the importance of the unique formula identifier (UFI) in the identification of mixtures and discussed the actors included under the concept of 'duty holder'. She then explained how information can be prepared in IUCLID and submitted through the different submission channels (the ECHA submission portal and national systems available for some MSs). Finally, she discussed the European product categorisation system (EuPCS), which is used to describe the main intended use of a mixture for which a submission has to be made according to Article 45 and Annex VIII to the CLP Regulation.

Discussion

One NHD asked whether the BPR authorisation holder would need to submit a poison centre notification. ECHA clarified that the obligation lies with the legal entities that are responsible for placing the product on the market and, as such, the authorisation holder would need to submit a notification. It was then explained that if the same product is placed on the market by different legal entities, each of them would need to make their own notification. Cefic inquired further by asking about the use of the UFI by different legal entities placing the same composition of biocidal product on the market. It was pointed out that, in such cases, the UFI can be re-used.

Another NHD asked whether the precursors of *in situ* generated products would be subject to notification. ECHA noted that if the precursor is placed on the market, it would need to be notified. In addition, she explained that the EuPCS does not contain an option to select a 'precursor' as a main intended use and that in some instances, the EuPCS may need to be assessed on a case-by-case basis. The Commission complemented by indicating that, from the BPR perspective, if a precursor is placed on the market with a biocidal intention, it would correspond to the biocidal product and, as such, it needs to be notified. Further reflection may be needed for cases where the precursor is not marketable and the biocidal product corresponds to the *in situ* generated active substance.

ECHA asked whether BPR treated articles would be subject to a notification in the case where

a treated article corresponds to a mixture. The speaker confirmed that the obligation to notify applies if the treated article is a mixture, for example, in the case of paints, but not if the treated article corresponds to an article.

3. Break-out groups

3.1 Possible cooperation of national helpdesks with industry associations and involvement in sharing answers to re-occurring questions

In the plenary session, the Chair introduced the breakout groups and gave the floor to Camelia MIHAI (Cefic), as the idea of this breakout group came from the previous BPR Workshop of May 2022, under agenda item 2.1 dealt by Biocides for Europe and A.I.S.E. (see the minutes).
Both organisations made a proposal to be involved in spreading the answers to re-occurring questions to their members through their communication channels. The aim of the break-out group discussion was to brainstorm on how this cooperation could be organised in practice, if NHDs would be willing to share their replies with industry organisations, what topics could be included in such cooperation and what could be the role of ECHA.

The speaker first introduced Biocides for Europe as a sector group of Cefic and A.I.S.E and the divisions of the members between both organisations. She presented the activities to support their members and gave an overview of the nature of questions that both organisations receive and reply. Camelia also highlighted what type of questions are not covered by their support; in particular, their frequently asked questions are related to difficulties in finding an evaluating competent authority, data protection expiry date (Article 95(5)), transitional measures and national laws (Article 89 (2) of the BPR).

During the break-out groups the national helpdesks generally showed interest in this enhanced cooperation, welcoming the possibility to brainstorm with colleagues on frequently asked questions and/or hot topics. They also agreed to the possibility to involve industry organisations, so those could then transmit to their member the agreed approaches/replies to FAQs in order to reduce the number of questions coming in. Moreover, they also welcomed ECHA's proposal to offer a platform, in the form of a recurring (e.g. quarterly to start with) video conference (VCN), where questions could be brought in advance and then discussed. The Commission also saw this as beneficial, underlining that those topical issues could be brought then to the CA meetings. The Commission outlined however that they needed to check internally if they would be able to join the VCN. ECHA committed to investigate further the possibility of a VCN, to be possibly initiated in 2023, with a survey.

It was discussed that the ECHA web page that collects links to BPR national requirements applicable during the transitional period could be improved by adding a short paragraph in English summarising the national requirements in each Member State and by updating the links, where outdated. This idea came from the fact that the national helpdesks reported in the working group that they are frequently contacted with questions concerning the transitional period and BPR national requirements, hence it would be useful to be able to refer to the ECHA page with updated links (to be provided by the NHDs themselves to ECHA). ECHA committed to take a

further look at the page and come up with a proposal.

Action points

To improve the ECHA web page that collects links to BPR national requirements by adding a short paragraph in English, summarising the requirements, and by updating links, where necessary.

To launch a written procedure about organising videoconferences – involving observers and the Commission – for exchanging views on recurring BPR questions, sharing and harmonising answers, and discussing new Q&As.

3.2 An overview of the current trends and hot topics among national helpdesks

In terms of hot topics, NHDs indicated that national authorisations, transitional measures and national fees continue to represent the most frequently asked enquiries they receive. Several participants mentioned that questions related to scope borderline cases and *in situ* biocidal products continue to be challenging and difficult to answer. These questions may concern, for example, the borderline between the BPR and cosmetics, medical devices or detergent legislation. Questions related to ozone or free radicals also remain quite complex.

It was noted that in some cases, scope questions were referred to the Commission, in accordance with Article 3(3) of the BPR as, for example, the case of monitoring traps for moths. However, the case is not yet definitively solved. It was also noted that scope questions are highly debated and may end up as court cases, e.g. Söll judgment.

Other questions for which NHDs receive enquiries concern rodenticides, insecticides and treated articles. Candidate countries also receive questions related to the transposition of the BPR to their national law. In terms of language and ways of working, all NHDs confirmed that they reply in their respective national languages and in English, and responses are delivered either by email or phone calls. In addition to responding to helpdesk enquiries, some NHDs are also involved in evaluation work and social media/communication activities.

During the discussion, it was suggested that it would be beneficial to compile the CA meeting documents into a comprehensive guidance document as it is currently difficult to navigate through the pieces of information captured in the individual CA documents. Additionally, it was pointed out that a training session on *in situ* products would be useful. In this regard, ECHA clarified that the *in situ* guidance document is expected to be published next year, in Q2.

Closing the BPR Workshop

The Chair listed the action points as the outcome of the workshop and thanked participants for the interesting discussions. She invited the participants to reply to the satisfaction survey which will be sent after the meeting and closed the BPR Workshop, until the next one foreseen for Spring 2023.

Annex I – Agenda of the BPR Workshop

BPR Workshop

Chair: Elena BIGI

BPR Workshop (9:30-16:15)

Opening by the Chair

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission (DG SANTE, Ligia NEGULICI)

1.2 Update from ECHA (ECHA, Claudio PUTZU)

1.3 Enforcement activities of the Forum BPR Subgroup (ECHA, Nicola TECCE)

1.4 Legal update (ECHA, Camilla BUCHANAN)

1.5 Hot topics from the ECHA Helpdesk (ECHA, Malgorzata SZKLAREK)

2. Topics proposed by national helpdesks

2.1 An overview of Poison Centre Notification obligations and biocidal products (ECHA, Heidi RASIKARI)

3. Break-out groups

Introduction by moderators

3.1 Possible cooperation of national helpdesks with industry associations and involvement in sharing answers to re-occurring questions – follow-up of the BPR Workshop in May 2022 (Cefic, Camelia MIHAI)

3.2 An overview of the current trends and hot topics among national helpdesks (ECHA, Anisa KASARUHO)

Summary of the break-out group discussions

Conclusions of the day

Closing the BPR Workshop

Annex II - Action points

No	Action	Agenda item	Responsible	Status
1.	Check with the Working Group - Efficacy whether there is a guidance update related to efficacy requirements for air disinfection.	1.2	ECHA	Closed
2.	Share with the HelpNet members (BPR confidential folder in S-CIRCABC): - The summary of the BEF-2 Workshop (June 2022) - The 'Guide for inspectors on control of online sales' resulting from the REF-8 recommendations - The 'BPRS Manual of Conclusions'	1.3	ECHA	Closed
3.	Improve the ECHA web page that collects links to BPR national requirements by adding a short paragraph in English summarising the requirements and by updating links, where necessary.	3.1	ECHA	Ongoing
4.	Launch a written procedure vote about organising videoconferences - involving observers and the Commission - for exchanging views on recurring BPR questions, sharing and harmonising answers, and discussing new Q&As.	3.1	ECHA	Closed

Annex III - List of participants

Country	Name, surname
Austria	Peter SCHINDLER
Croatia	Ivana VRHOVAC FILIPOVIC
Denmark	Lone KÆRGAARD
Estonia	Riina LAHNE
Finland	Hannu MATTILA
France	Romy COLLET (remote)
Germany	Juliana REY (remote)
Greece	Vasileios VAGIAS
Hungary	Henrietta SZABÓ
Ireland	Louise PIERCE (remote)
	Mervyn PARR (remote)
Italy	Renato CABELLA (remote)
Latvia	Evija PORIKE
Netherlands	Cindy VAN DER MEER
Norway	Jorid FRYDENLUND
Poland	Łukasz BELKIEWICZ
	Agnieszka BARANOWSKA-MOREK (remote)
Romania	Simona DRĂGOIU
Slovak Republic	Jana CHMELIKOVA (remote)
	Maria SKULTETYOVA (remote)
Slovenia	Marta PAVLIČ ČUK
Spain	David CANO GOMEZ
Sweden	Anneli RUDSTRÖM

European Commission

DG	Name, surname
DG SANTE	Ligia NEGULICI

Third Country observers

Country	Name, surname
Montenegro	Nevena BOGAVAC
	Tatjana MUJIČIĆ
Serbia	Jelena GRUJIC
Switzerland	Olivier BLASER
Türkiye	Okan KUMCU

Industry observers

Organisation	Name, surname
Cefic	Camelia MIHAI

ECHA staff

Unit[2]	Name, surname
A2	Anisa KASARUHO
	Elena BIGI
	Erwin ANNYS
	Evelyne FRAUMAN
	Gary WATKINS
	Malgorzata SZKLAREK
	Nicola TECCE
	Roxana BROASCA
	Ruben GONZALEZ VIDA
C1	Anna-Liisa PIKKARAINEN
E2	Camilla BUCHANAN
D1	Claudio PUTZU
A3	Heidi RASIKARI
R3	Marko POPOVIC

[2] ECHA – organisation : https://echa.europa.eu/about-us/who-we-are/organisation