# Minutes of the 16th HelpNet Steering Group meeting and regulatory workshops

**Time:** 2-5 November 2021

**Platform:** WebEx

***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.*

## Contents

# The 16th HelpNet Steering Group meeting

The HelpNet 16 events, organised for the members and observers of HelpNet, took place from 2 to 5 November 2021 on the WebEx platform.

This document summarises the topics discussed during the Steering Group meeting and the regulatory workshops (Annex I) and the follow-up action points set (Annex II). The names of the participants attending the HelpNet 16 events are listed in Annex III to these minutes.

## 1. Opening the Steering Group meeting

### 1.1 Opening by the Chair of HelpNet

The Chair, Erwin ANNYS (ECHA) opened the 16th Steering Group meeting and welcomed representatives of the national helpdesks, observers from candidate and third countries, observers from industry and additional experts.

He then referred to the present circumstances, under which ECHA can only organise virtual meetings, due to travel restrictions in Europe related to COVID-19.

The Chair introduced the changes in the unit since June 2021: staff joining the unit Amandine JOMIER and Eduardo BARRETO TEJERA; leaving the unit: Christina LOUKOU and Helena JÄRNSTRÖM; and the upcoming changes in the top management.

### 1.2 HelpNet 16 - follow-up of action points

The Chair presented the list of action points from the previous Steering Group meeting in November 2020. All action points were closed.

### 1.3 Approval of the HelpNet 16 draft agenda

The Chair introduced the draft agenda which was adopted without further comments.

## 2. Updates from the HelpNet Secretariat

### 2.1. Upcoming annual survey on helpdesk activities - tips

Viorica NAGHY (ECHA) introduced the national helpdesk (NHD) report on 2020 activities, and tips and changes proposed for the survey to be launched in early January 2022.

Since 2018, a public version of the annual report is published on ECHA's website while the internal version is available for members and observers in S-CIRCABC.

A new section, 'Annual ECHA helpdesk activities', was included in the 2020 report highlighting the number of regulatory enquiries replied by ECHA helpdesk on BPR, CLP, and REACH and complementing the 80 000 enquiries answered by the NHDs; the most frequent topics asked by the customers and the trends observed since 2017; the support given to companies with a focus on guidance updates; development of new Q&As; the events organised by ECHA and the HelpNet Secretariat. All these activities were mirroring activities reported by 30 EU/EEA countries, two EU candidate countries to EU membership, and one third country.

As the information submitted by NHDs through the annual survey triggered some requests for clarification, some tips were given for the upcoming survey, e.g. a new way of ranking the hot topics.

The current tool used for the annual survey will be replaced with EU Survey, therefore, the launch will be slightly delayed. NHDs may expect to receive the survey in early January 2022, with a deadline set in mid-February. In the survey and the report on 2021 activities, the new ways of working will be addressed.

## 2.2. Report on unsolved/timed-out questions

Roxana BROASCA (ECHA) introduced the HelpEx reports issued twice per year, including a list of unsolved and timed-out HelpEx questions for each of the three regulations.

In 2021, HelpEx discussions and consultations resulted in three additional unsolved questions and 24 timed-out questions. Thus, the HelpNet Secretariat wished to discuss with the NHDs how to reduce the number of unsolved/timed-out questions and whether the Secretariat can take the initiative to close questions after a certain period of time (see results of the poll in Annex IV).

## 2.3 HelpNet update on new ways of working

Elena BIGI (ECHA), Team Leader of the Regulatory Advice Team (REST), gave an update on the new ways of working (NWOW), specifically on how the dispatch of REACH and CLP EU-and non-EU related enquiries started on 1 September and 6 October, respectively.

Questions related to the SCIP database and PIC-related questions will remain mainly in ECHA's remit. Moreover, the BPR division of tasks remains unchanged.

The NWOW was discussed in the REACH and CLP workshops in June 2021. A reduction of 1.5 FTEs in the ECHA Helpdesk and HelpNet was indicated in 'ECHA Programming Document(s) 2021-2024'[1] requiring ECHA to forward part of the questions received by the Agency to NHDs.

A recap of the criteria for redistribution of enquiries to NHDs, scenarios on how questions will get to NHDs, and statistics on the number of enquiries forwarded to NHDs in September and October were presented. In this context, the new ECHA landing pages will allow a non-EU company to select a Member State of interest, from a drop-down list. This could facilitate the re-direction of non-EU questions by ECHA, together with the criteria and fair overall distribution criteria.

Elena BIGI introduced the results of the survey on the NWOW, particularly the feedback received from NHDs, and shared the first reactions received from customers on the NWOW.

The speaker also provided feedback from the Safer Chemicals Conference 2021 and the ECHA Helpdesk stand. More than 2 000 people from all over the world joined the event on 6 October 2021 to share insights on chemicals. Videos and presentations are available on ECHA's website[2].

The ECHA Helpdesk's stand got quite some visitors during the day, the questions were topic-related (PCN, SCIP, REACH) but not on the NWOW. The video[3] and the presentation[4] of both the regulatory and technical support on IT tools (iTex) helpdesks are publicly available.

Finally, a look to the future on how to report and continue implementing the NWOW, and better cooperate within the network was addressed (see results of the poll in Annex IV).

---

1 https://echa.europa.eu/documents/10162/8633921/FINAL_MB_56_2020_%282%29_Programming_Document_2021-2024_MB60.pdf/74ee80c7-26e9-e000-270c-5ac83e59d185

2 https://echa.europa.eu/-/safer-chemicals-conference

3 https://www.youtube.com/watch?app=desktop&v=gcr-UFKKHuQ

4 https://echa.europa.eu/documents/10162/10543934/meet_the_helpdesks_211006_en.pdf/39414e7f-70e4-9596-978a-7a67f9465c9a?t=1633525641745

**Discussion**

Representatives of NHDs discussed about the transfer of enquiries under the NWOW, reports expected from NHDs on the NWOW and some practicalities when enquiries are forwarded to NHDs or answer shopping enquiries. NHDs considered that if answer shopping becomes an issue, the matter should be dealt with in a similar way as previously i.e. by posting the questions in the HelpEx tool.

ECHA clarified that no specific reports are expected from the NHD colleagues, but whenever possible NHDs could provide a qualitative estimate on the new questions that arise due to the NWOW.

In the next REACH and CLP workshops, ECHA will provide a mid-year report showing how the redistribution went in 2022 (Q1 and Q2). Based on regular reports issued by ECHA and feedback received from the NHDs, the functioning of the NWOW and its criteria will be looked at in one year's time and possibly discussed at the next HelpNet Steering group meeting.

### 2.4 Role of HelpNet – new ways of working and how to increase harmonisation and cooperation

Elena BIGI (ECHA) introduced the current role of HelpNet and some suggestions for increased cooperation between ECHA and NHDs, e.g. increasing the use of ad hoc working groups, continuing to organise training sessions and videoconferences on topics of interest raised by NHDs, increasing cooperation in developing new Q&A material. A new pilot project facilitating the work in the development of Q&As was presented by Elena BIGI and the idea of involving the NHDs in ad hoc Q&A reviews was proposed.

To enhance harmonisation in specific areas, the use of ad hoc working groups and videoconferences was then discussed. It was stated that even if not all NHDs would be actively involved in the meetings, all would benefit – same as the videoconference on REACH and CLP.

The preferred means of increasing cooperation and harmonisation of responses between NHDs are presented in the results of the poll (Annex IV).

## 3. Updates from ECHA

### 3.1 Communication activities

Johanna SALOMAA-VALKAMO (ECHA), the Head of the Communications Unit, was presenting the latest and the most important communication activities relevant for HelpNet:

- EU campaign for parents on UFI matters started on 8 November 2021;
- the launch of the SCIP[5] database in mid-September;
- enforcement projects and upcoming communication on the results of the online sales enforcement project (REF-8) at the end of 2021;
- news on nanomaterials (EUON); and
- podcasts[6] targeted to expert audiences and anyone who has an interest in how chemicals affect human health and the environment.

The speaker provided feedback from the Member State Communicators' Network meeting on 28 October 2021 and the main topics on the agenda, including the tattoo campaign.

Representatives of the NHDs showed interest in the campaigns and asked for more details on the UFI and tattoo ones. A representative of an NHD noted the high number of questions received from tattoo artists concerning inks excluded from the market, and stocks at their

[5] https://echa.europa.eu/scip
[6] https://echa.europa.eu/podcasts

premises. The speaker stressed that the current campaign is targeted at the general audience and not professionals.

Another correspondent, participating in the Member State Communicators' Network meeting asked if a merge between the Risk Communicators' Network and the Member State Communicators' Network would be possible.

Johanna SALOMAA-VALKAMO clarified that the Member State Communicators' Network has been set up as an interactive, informal forum where professionals in communications activities from the Member States and ECHA can exchange ideas, best practice, and information on various topics related to chemicals. Member State communicators act as multipliers, increasing outreach of both ECHA's and local campaigns. The merge with the Risk Communicators'' Network, currently put on hold, could be beneficial but not planned so far.

## 3.2 Forum activities

Maciej BARANSKI (ECHA) provided an update on the Forum 2019-2020 activities; cross-cutting and REACH, CLP and BPR priorities; REACH Review 2017 and the stakeholders' engagement and training sessions organised for inspectors:

- Control of imports and cooperation with customs in enforcement of REACH restrictions and CLP labelling[7]. Selected controls were performed on imported goods: (a) articles for which the presence of a substance restricted by REACH Annex XVII was checked, for example, jewellery and other metal and plastic articles; and (b) mixtures, for which the classification and packaging requirements were examined. A *Practical guide on cooperation with customs in enforcement of REACH restrictions and CLP labelling* was delivered.
- Integrated enforcement (REF-10) addressing: REACH and POPs restrictions; REACH duties for substances in articles, RoHS and Toys Directive. Inspections start in January 2022 with a focus on materials and product categories common for consumer products.
- Internet sales of chemicals (REF-8) addressing: REACH restrictions and safety data sheets; CLP provisions on advertising; and BPR duties related to authorisation of products and advertising. Very high non-compliance rates were detected. Report[8] planned for end of 2021.
- Pilot project on registration exemption for recovered substances duties, with manual delivered and inspections ongoing in 2021.
- Enforcement of ECHA decisions ('Interlinks') – Forum delivered a second edition of the *Interlinks Guide for communication on enforcement cases between the National Enforcement Authorities and ECHA*.
- *Guide for inspectors on enforcement of registration duties* was released following the findings of the project on control of registration (REF-7).
- Supply chain communication project (REF-11) to start in 2022 focusing on quality of information in safety data sheets, as required by recently updated Annex II to REACH.
- CLP pilot project on classification of mixtures planned to start in November 2021.

[7] https://echa.europa.eu/documents/10162/17086/customs2_project_report_en.pdf/5a2c3795-7ed9-5900-fe28-540228abc7c1

[8] Post meeting note: The report was published on 9 December 2021: https://echa.europa.eu/documents/10162/17088/project_report_ref-8_en.pdf/ccf2c453-da0e-c185-908e-3a0343b25802?t=1638885422475
Press release and podcast: https://echa.europa.eu/-/majority-of-inspected-products-sold-online-breach-eu-chemicals-laws

- BPR enforcement project on treated articles (BEF-1) with a report[9] published in December 2020 and a *Practical guide for inspectors on control of treated articles* issued in 2021.
- Action 13(2) of the REACH Review 2017 requesting Member States to establish comparable parameters on enforcement. Forum is expected to conduct a two-year pilot of voluntary annual reporting of national enforcement activities to ECHA. Timelines are still to be agreed.
- Remote workshop organised for accredited stakeholder organisations to discuss the results of Forum projects finished in 2020: BEF-1 on treated articles, REF-7 on registration, and a pilot project on import controls for restriction and labelling.

**Discussion**

Regarding who should be legally responsible for the non-conformity of products sold online, Maciej BARANSKI clarified that the responsibility is on the seller established in one of the Member States. As an example, larger operators had to withdraw the non-compliant articles sold through their portals.

## 3.3 Feedback from ECHA on Chemicals Strategy for Sustainability

Erwin ANNYS (ECHA) gave an update on the actions taken after the adoption[10] of the European Commission's Chemicals Strategy for Sustainability (CSS) and the presentation given by Elena MONTANI at the HelpNet 15[11] in October 2020.

The CSS is the step towards a zero-pollution ambition for a toxic-free environment announced in the European Green Deal and includes several areas where ECHA also contributes. There are 11 active working groups which are covering 15 departments (DGs) of the European Commission and four EU agencies.

The strategy strives for a toxic-free environment, where chemicals are produced and used in a way that maximises their contribution to society including achieving the green and digital transition, while avoiding harm to the planet and people and the production and use of sustainable chemicals becomes the EU market norm and a global standard.

All the different projects were grouped in five building blocks: innovation, competitiveness, recovery; strengthening legislation for better protection; simplification and coherence; knowledge and science; and global. The key actions were materialised in three clusters:

- Knowledge – based on REACH registrations, OSOA[12] principle, looking at the identification of hazards and tracking substances of concern, and having information on indicators on the progress and (bio)monitoring.
- EU legislation: looking at generic risk assessment and what is considered essential use in the EU, mixture assessment factors and the strong statements: zero tolerance to non-compliance.
- Innovation: increasing investment and innovative capacity for production and use of chemicals that are safe and sustainable by design, and reflecting on:

[9] https://echa.europa.eu/documents/10162/17086/bef_1_report_en.pdf/8e0e4520-3c41-92d2-0e9f-199109ee8f5f
[10] On 14 October 2020
[11] https://echa.europa.eu/about-us/partners-and-networks/helpnet/2020
[12] One substance, one assessment

- Sustainable finance[13] - the Commission workstream that supports the European Green Deal aim of channelling private investment towards the transition to a climate-neutral economy.
- EU taxonomy[14] - establishing a list of environmentally sustainable economic activities and directing investments towards these projects and activities.
- Strategic research and innovation policy[15] and stronger EU legislation.

The Chair informed on legislative revisions:

- The CLP revision, the proposal to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs and persistent and mobile substances, terrestrial toxicity and introduction immuno- and neurotoxicity.
- The REACH revision, the polymers registration, updates to Annexes VII to XI, information on volumes, uses, exposure/emissions, overall environmental footprint of chemicals, revocation of registration numbers and the authorisation/restriction and the interaction between the two processes.
- Revisions of other pieces of legislation: Food Contact Materials, Cosmetics, Toys, etc.

Ultimately, the European Commission will submit legislative proposals to the Council and the European Parliament.

Erwin ANNYS informed also on non-legislative measures, specifically the set up of a high-level roundtable[16] on the implementation of the CSS, and the next meeting scheduled on 25 November 2021 and where enforcement will be the point of discussion. Discussions will take place also on OSOA, criteria safe and sustainable by design, the strategic autonomy for critical chemicals, essential uses, indicators, and early warnings.

## 3.4 Updates from ECHA's report on the operation of REACH and CLP - Article 117(2) of REACH, Article 46 of CLP

Catherine CORNU (ECHA) presented the main findings from ECHA's report[17] on the operation of two central tools for managing the safety of chemicals in the EU – the REACH and CLP regulations; the key messages on the REACH and CLP processes; and the challenges and work to be done[18] to achieve the protection levels envisaged by the legislator.

The data collected in the last five years under REACH and CLP contributed to protecting Europe's workers, consumers, and the environment from the harmful effects of chemicals. The two regulations have also contributed to internal market functionality, competitiveness, and innovation.

85 % of EU citizens have concerns about the health impact of chemicals. Due to REACH and CLP data, they can now make informed choices when buying products and have access to better information to provide an emergency health response through poison centres.

Companies and citizens have better information on chemicals, allowing to prevent and reduce

[13] https://ec.europa.eu/info/business-economy-euro/banking-and-finance/sustainable-finance_en
[14] Taxonomy Regulation: https://ec.europa.eu/info/law/sustainable-finance-taxonomy-regulation-eu-2020-852_en
[15] https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/shaping-eu-research-and-innovation-policy_en
[16] https://ec.europa.eu/environment/news/chemicals-strategy-call-applications-high-level-roundtable-2021-03-04_en
[17] https://echa.europa.eu/documents/10162/17226/operation_reach_clp_2021_en.pdf/e271b3c8-137a-48ad-30ad-499249235ee5
[18] https://echa.europa.eu/report-on-the-operation-of-reach-and-clp-2021

impact on health and the environment:

- 91 chemicals were classified under CLP as 'hazardous to the environment';
- 71 chemicals were classified for their potential to cause cancer, genetic mutations or affect reproduction (CMRs);
- 6 chemical groups were limited or banned to reduce consumer exposure: tattoo inks, CMRs in textiles, methanol in windshield wiping fluids, inorganic ammonium salts, silanetriol and TDFAs, and 4 phthalates;
- 4 chemical groups were limited or banned under REACH to reduce environmental emissions - decaBDE, PFOA, D4 & D5, phenylmercury compounds;
- 3 chemical groups were limited or banned specifically to protect workers and children: NMP, BFA in thermal paper, diisocyanates;
- Several proposals for limiting chemicals with large-scale emissions are ongoing (e.g. microplastics).

Despite recognised progress, improvements are needed to ensure synergies between REACH, CLP, and other pieces of legislation. In this regard, the report identified areas where REACH and CLP can be improved as: information in the registration dossiers; communication on the safe use of chemicals; screening of registered substances, assessing if generation of more data or risk management measures are need; authorisation; restrictions; classification and labelling; animal testing; functioning of the internal market; financing and Member State support.

ECHA's report serves as the Agency's contribution to the European Commission's report, including the reviews of the CLP and REACH regulations.

## 4. Collaboration activities (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. If circumstances will allow, the next Steering Group meeting might take place in autumn 2022, when we would welcome all HelpNet members and observers to the new building of ECHA.

# 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 and observers. The names of the participants attending the REACH Workshop are listed in Annex III to these minutes.

## 1. Updates from the European Commission and ECHA

### 1.1 Update from the Commission, including the REACH review

Riccardo ZORGNO (European Commission, DG GROW) informed participants on recent legislative changes, amendments to be adopted soon, the state of play on authorisations and restrictions, and the REACH revision.

**Annexes VI to X**:

The Commission revised certain information requirements for registering chemicals under REACH. The written procedure for vote ended on 1 November 2021, and the changes in the Commission Regulation (EU) 2021/979[19] amending Annexes VI to X to REACH will start to apply in early 2022.

Other amendments to the REACH annexes which were published or pending publication:

**Annex XIV:**

- amendment adding entries 55 to 59 following ECHA's ninth recommendation (undergoing a written procedure for vote);
- amendment adding ED properties of four phthalates (undergoing adoption).

**Annex XVII:**

- polycyclic-aromatic hydrocarbons (PAHs) in granules or mulches used as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications (EU 2021/1199 of 20 July 2021 - published);
- perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances (OJ L 282, 5/08/2021, page 29–32 - published);
- carcinogenic, mutagenic or reproductive toxicant (CMR) substances (three months scrutiny ended - adoption pending);
- N,N-dimethylformamide (DMF) (pending adoption after three months scrutiny).

**Annex VII restrictions in the pipeline on:**

Cobalt salts; D4, D5, D6 siloxanes[20]; microplastics; skin sensitisers in textiles; substances in nappies; formaldehyde and releasers; calcium cyanamide in fertilisers; and lead in PVC. For the latter, after the positive vote in the REACH Committee, the European Parliament opposed this restriction under the Regulatory Procedure with Scrutiny in February 2020.

**Authorisation decisions:**

About 30 decisions under the drafting stage for OPE/NPEs substances, around 10 for chromium trioxide, 12 draft decisions related to the addenda on substitution plans and two applications/review report on DEHP to be updated by the applicants following the adoption of

[19] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32021R0979
[20] D4 (Octamethylcyclotetrasiloxane), D5 (Decamethylcyclopentasiloxane) and D6 (Dodecamethylcyclohexasiloxane)

the Annex XIV amendment on phthalates. Moreover, two draft decisions for bis(2-methoxyethyl) ether (diglyme).

In addition, there are 17 draft decisions undergoing a written procedure for vote for uses of: OPE/NPE, CTPht/AO, CTPht, and lead chromates.

Regarding the **revision of the REACH Regulation**, the speaker informed that the Inception Impact Assessments[21] were published and subject to public feedback until June 2021 (around 325 comments received). The assessment aimed to inform citizens and stakeholders about the Commission's plan and receive feedback and any relevant information that stakeholders, competent authorities, businesses, NGOs, academia, etc. may have. Open public consultation will open in early 2022, the impact assessment will be finalised in summer 2022.

The main horizontal points to be discussed are:

- Restructuring the authorisation and restriction processes: three options of different degrees to reform restrictions and authorisation; strengthening incentives for substitution; operationalising the concept of essential use and improving the interface with other pieces of legislation.

- Extending the generic risk approach for REACH restrictions: to endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs; products marketed for professional use; operationalising the concept of essential use in restrictions, including the criteria for granting derogations.

- Revision of provisions for control and enforcement: requirements for the design, organisation and implementation of national controls and enforcement, including stricter border controls; establishing a European Audit Capacity to audit Member States enforcement.

The proposal for the REACH revision will be available by end of 2022.

### Discussion

One correspondent highlighted that timelines for the REACH revision are challenging. Riccardo ZORGNO confirmed that timelines are indeed tight, with the finalisation of the impact assessment by mid-2022; studies and public consultations started these months, all to be concluded by the end of next year.

## 1.2 Guidance on registration

Alexis QUINTANA-SAINZ (ECHA) presented the update process of the *Guidance on Registration* and the main changes in the revised guide.

The updating process started in 2020, with the consultation procedure initiated in September based on the first ECHA draft. The meeting with the Partner Expert Group (PEG) took place in January 2021, and with Forum and the competent authorities in March, respectively May. The revision of the *Guidance on Data Sharing* started in parallel, but discussion are still ongoing.

To ensure that the guidance updating process[22] is kept transparent and open to the participation of relevant partners, the drafts and the feedback received during the various

[21] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en
[22] Consultation procedure for Guidance documents: https://echa.europa.eu/documents/10162/17207/pro-0011_consultation_procedure_for_guidance_en.pdf/21fa2b20-60cc-481e-833b-9afbee9ac966

consultation steps were published on ECHA's website[23].

About 400 comments were received from PEG, Forum and CARACAL and 2/3 of the proposed changes were accepted by ECHA. Finally, the updated *Guidance on Registration* was published[24] in August 2021.

The speaker noted that the comments received on the registration of nanoforms will be addressed in the Appendix for nanoforms applicable to the *Guidance on Registration* and substance identification[25].

Alexis QUINTANA-SAINZ highlighted the main changes in the *Guidance on Registration*:

- End of phase-in and end of registration deadline. Alignment with the Commission Implementing Regulations on the (i) application of certain registration and data-sharing provisions of REACH after the expiry of the final registration deadline for phase-in substances and (ii) duties placed on registrants to update their registrations under REACH.
- Extended information on the notification of a cease of manufacture or import.
- Explaining when a registration is no longer valid.
- Alignment with the *Guidance on data-sharing*: data-sharing section moved and section on joint submission of data expanded.
- Bringing further clarifications and examples on the roles and duties of only representatives.
- Re-imported substances: explanation of the examples (mixtures).
- Implementing regulation on dossier updates with detailed explanation of the deadlines to submit an update.
- Notification of cease of manufacture or import and legal consequences of the cease of manufacture depending on whether ECHA is notified of the cessation while ECHA processes an evaluation decision or outside of that period.

The *Guidance on Registration* will be translated in all EU languages and will be available by the end of 2021 or the beginning of 2022.

## 1.3 Unclaimed NONs project

Maria Jose BELMONTE SANCHEZ (ECHA) presented the project on unclaimed Notifications of New Substances (NONS). NONS was the procedure to notify chemical substances to EU Member States before the advent of the REACH Regulation (Article 24) and following EC Directive 67/548. The notification in accordance with Directive 67/548/EEC was regarded as a registration and ECHA assigned 9 963 registration numbers by 1 December 2008.

Over the past 12 years, 5 225 NONS registration numbers were claimed by their owners, thereby confirming them as registrations under REACH. After the initial peak of NONS claimed in 2008-2010, NONS registration numbers declined to about 4 per year with 4 739 NONS registration numbers still unclaimed.

According to ECHA's newly published five-year report: 92 % of NONS do not contain the standard information requirements according to REACH, and so far only 8 % of NONS registrations have been updated to increase the tonnage band. In addition, 48 % of these

[23] Ongoing guidance consultations: https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach
[24] https://echa.europa.eu/guidance-documents/guidance-on-reach
[25] https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/f8c046ec-f60b-4349-492b-e915fd9e3ca0

NONS registrations are 'unclaimed NONS', i.e. NONS notifications for which no company has claimed ownership after they became registrations under REACH.

The top five countries with unclaimed NONS have 2 352 unclaimed NONS, and this number is not including the UK unclaimed NONS[26].

On 21 September, REACH national helpdesks were informed that ECHA will end the possibility for companies to claim the registration numbers assigned in 2008 to their NONS notifications. Companies wanting to claim the registration numbers assigned to their NONS notifications will have six months since ECHA will launch the campaign. Afterwards, registration numbers that have not been claimed will no longer be valid. This information was communicated to the NHDs in September but is still not in the public domain.

HelpNet was also consulted on the revision of NONS Q&As published on ECHA's website.

Maria Jose BELMONTE SANCHEZ concluded that some of the Member State competent authorities may receive questions after the launching of the project on ECHA's website and REACH-IT, and hopefully many NONS will be claimed (although there is no obligation to claim the registration number assigned to the NONS), and companies will decide to update their registrations.

**Discussion**

Regarding unclaimed NONS and the ending of the period to claim them, ECHA clarified that the classification of the registration numbers in ECHA's database (REACH-IT and dissemination pages) will be updated to indicate which NONS notifications were not claimed, once the project is concluded.

ECHA will carry out the NONS clean-up operation next year and welcomes any initiative taken by Member States in raising awareness and supporting local companies requesting migrating the SNIF[27] files to the IUCLID file[28].

Regarding the communications campaign, Maria Jose BELMONTE SANCHEZ mentioned the foreseen news on ECHA's website, dedicated post in the social media and the newsletter sent to ECHA's accredited stakeholders, and information in REACH-IT available for all companies through the new section in the main page.

## 1.4 Latest update from evaluation

Katrin HALLING (ECHA) presented the latest updates from evaluation, specifically on the following main topics: clarification of REACH annexes, working with groups of substances, evaluation in numbers and the EOGRT studies (review project and critical aspects).

The Commission amended certain provisions in the REACH annexes[29] to provide more clarity on the obligations of registrants and make ECHA's evaluation practices more transparent and predictable. The main changes are outlined in ECHA's news[30]. A few examples are given below: Standard Information Requirements:

[26] Post meeting note: UK unclaimed NONS can be claimed by EU companies. UK NONS claimed that were transferred: 519. UK NONS claimed that were not transferred and have been revoked: 779
[27] Summary Notification Interchange Format File
[28] How is the NONS information transferred from SNIF to IUCLID 5? See reply on ECHA website, Q&As section: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/NONS-Registrants+of+Previously+Notified+Substances
[29] Regulation (EU) 2021/979 came into effect on 8 July 2021 and applies from 8 January 2022.
[30] https://echa.europa.eu/-/upcoming-changes-to-reach-information-requirements

- Annexes VII to X (introductory part): Testing to be performed at appropriately high dose levels.

Annex XI to REACH sets out the general rules for adaptation of the standard testing regime set out in Annexes VII to X.

- 1.1. Use of existing data: data generated as from 1 June 2008 not to be considered as existing data.
- 1.2. Weight of evidence: how it can be applied and how it should be documented.
- 1.5. Grouping of substances and read-across approach: What documentation is required. Structural similarity for UVCB substances.

Working with groups[31] of substances aims to speed up the work under ECHA's Integrated Regulatory Strategy[32], bring consistency and target the right substances at the right time. Detailed figures were provided for substances screened in 2014-2018 and assessed through the grouping approach in 2019-2020; and the number of substances for which follow-up actions proposed in group assessment were concluded in 2020. Conclusions of the group assessments will be publicly available on ECHA's website (the first batch[33] in December 2021). Information on the progress made in dossier and substance evaluation in 2020 can already now be found on ECHA's website [34].

Katrin HALLING presented some critical aspects for designing and conducting extended one-generation reproductive toxicity (EOGRTS) studies under REACH. ECHA's advice on improving EOGRT studies is available in the clarification note[35] linked to the ECHA Weekly[36] bulletin of 7 July 2021. Experts from ECHA and Member States are currently evaluating study reports in the EOGRTS review project.

As regards to the support to registrants, helpful links when replying to customers were provided:

- Practical guides on dossier and substance evaluation
- Practical guide: How to use alternatives to animal testing
- Q&As
- Recommendations to registrants
- Dossier evaluation status page to monitor substances
- CoRAP, PACT and other material for information on authorities' priorities and plans.

## 2. Updates from ECHA

### 2.1 Restrictions update

Augusto DI BASTIANO (ECHA) gave an update on ongoing restrictions under preparation and opinion development, upcoming restriction proposals expected to be received in 2022, and relevant activities performed in 2021 in the field of restriction.

The restrictions concerned the following substances:

[31] https://echa.europa.eu/working-with-groups
[32] https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2020_en.pdf/646c8559-360d-f6ab-bfb7-02120eab52fa
[33] https://echa.europa.eu/-/first-assessments-of-regulatory-needs-for-groups-of-chemicals-published
[34] https://echa.europa.eu/further-information-requests-2020
[35] https://echa.europa.eu/documents/10162/17228/critical_eogrts_info_en.pdf/
[36] https://echa.europa.eu/view-article/-/journal_content/title/echa-weekly-7-july-2021

- Restrictions in opinion development phase: dechlorane plus, 2,4-Dinitrotoluene, lead in shots and fishing sinkers, substances in nappies, polycyclic aromatic hydrocarbons (PAH) in clay targets, undecafluorohexanoic acid**,** its salts and related substances (PFHxA).
- Restriction intention: BPA (previously restricted in thermal paper) and other bisphenols (BPs); N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP); per- and polyfluoroalkyl substances (PFAS) covering firefighting foams (FFF) among other uses.
- Restriction proposals prepared by Member States and ECHA: BPA – April 2022; DMAC/NEP – April 2022; PFAS – in fire fighting foams (FFF) – January 2022; PFAS (wide range of uses) – July 2022; medium-chain chlorinated paraffins (MCCP) – July 2022, and creosote in treated articles – January 2022.

Regarding the restriction activities in 2021, ECHA published investigation reports on recovered PVC containing cadmium (entry 23), substances (other than PAHs) in infill material and ECHA's restriction dossiers prepared according to Article 69(2) of REACH including new SCIP data.

Finally, Augusto DI BASTIANO mentioned the support provided by the restriction team to ECHA's helpdesk secretariat from January 2021 to date. The most popular topics addressed were: microplastics, PFAS (including PFHxA, PFOA) and the publication of the sixth batch of Q&As on restrictions.

## 2.2 Persistent organic pollutants

Ignacio GONZALEZ RODRIGUEZ (ECHA) presented what persistent organic pollutants (POPs) are, the main objectives of the international treaties on POPs (the Stockholm Convention and the Aarhus Protocol) and how these are implemented in the European Union by i.e. the POPs Regulation[37].

The recast of the POPs Regulation (EU) 2019/1021 introduced a series of tasks for ECHA and the Forum. In summary, these are:

- Support the Commission and the Member States to identify and propose new substances meeting the criteria for listing in the Stockholm Convention.
- With the agreement of Commission, provide the Member State competent authorities (MSCAs) and the members of the Forum as well as stakeholders as appropriate, with assistance and technical and scientific guidance to ensure the effective application of this regulation.
- Compile and process information from the MSCAs on the implementation of the regulation and publish a Union overview.
- ECHA's Enforcement Forum coordinates a network of MSCAs that are also responsible for enforcing the regulation.

The speaker summarised the process for the proposal of new substances to the Stockholm Convention (both by the EU and other parties to the Convention) and the role of the Persistent Organic Pollutants Review Committee (POPRC).

Ignacio GONZALEZ RODRIGUEZ reflected on the role of the competent authorities expert group[38] for POPs. The purpose of the expert group is to coordinate the work on POPs among the Commission, the MSCAs and ECHA as well as to exchange information on various matters related to the implementation of the regulation. There are a wide range of topics covered in the meetings, including the identification, and listing of new substances, the preparation of

[37] Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02019R1021-20210315 https://echa.europa.eu/pops-legislation

[38] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=1656&Lang=EN

delegated acts for the amendment of the annexes of the POPs Regulation and interpretation of the provisions of the POPs Regulation.

The speaker also presented to the expert group a summary of the types of questions received by its helpdesk and highlighted that a first set of 21 Q&As on POPs have been published on ECHA's website. The Commission, in collaboration with the MSCAs and ECHA, is finalising two documents which will provide an agreed interpretation of Articles 4(2) and Article 5 of POPs. ECHA aims to publish those documents on its webpage once they are adopted.

The speaker presented the interlinks of the POPs and REACH regulations, with examples of the regulatory actions taken under REACH for POP substances and how these may later be superseded by the POPs Regulation. The speaker highlighted that for those cases when a REACH restriction is adopted prior to the listing of the substance under the Convention, a technical amendment to REACH Annex XVII is prepared to remove the specific entry after the listing in the POPs Regulation.

In relation to pesticides, the speaker noted that EU proposals will only be prepared for active substances for which a decision for non-renewal of the approval has been adopted under the Plant Protection Products Regulation or which have already been phased out in the EU. Recent examples of EU proposals on PPP are methoxychlor and chlorpyrifos.

**Discussion**

One HelpNet correspondent indicated that it would be useful that ECHA publishes a unique list containing all substances restricted under POPs and REACH. ECHA replied that indeed there are two lists, one list with substances included in the annexes to the POPs Regulation and the list of substances proposed for inclusion in the Convention are published on ECHA's website. However, the POP process is incorporated in the ACT table[39], meaning that for a substance in the table, duty holders can see all the ongoing regulatory processes, including the POPs.

The Chair added that chemicals are regulated in the European Union by several pieces of legislation, not only REACH and POPs, and that the EU Chemicals Legislation Finder[40] (EUCLEF) provides an overview of the pieces of legislation that apply to each chemical.

The Chair also noted that on (open) groups of substances subject to restrictions, ECHA normally provides a non-exhaustive list of identifiers (EC, CAS numbers). Depending on the CAS number of the substance used, the regulatory obligations are intrinsically the responsibility of industry.

## 2.3 Overview of the ECHA Helpdesk hot topics

Carmen KLAUSBRUCKNER (ECHA) presented an overview of hot topics in different areas of REACH, with a focus on questions related to registrations and questions triggered by the SCIP obligations.

The ECHA Helpdesk saw an overall increase in REACH-related (including SCIP) questions in comparison to the first three quarters of 2020 of about 15 %. Most REACH-related questions received were on registration (including obligations, PPORD, information requirements, exposure assessment, CSA/CSR, intermediate, supply chain), followed by evaluation and authorisation related enquiries.

An increase in questions on evaluation was observed and SCIP questions still account for a

[39] Accessible for Member State competent authorities. The POPs process is not yet incorporated into the Public Activities Coordination Tool (PACT), which is the public version of ACT.
[40] https://echa.europa.eu/legislation-finder

substantial share of the total amount of incidents received.

For authorisation, the chromium VI decisions in December 2020 triggered questions on downstream user notifications. OPE/NPE cases related to exemption and the extension of deadlines for OPE for COVID-related cases created the need for clarification for some industry actors.

Substance identification questions are still mainly on Annex V, polymers/monomers and nanoforms of substances; an increasing number come in as cross-process questions, mainly in the context of SVHC identification, POPs, or restrictions.

Industry stakeholders affected by evaluation processes enquire about the possibility of an extension of deadlines, the consequences of cease of manufacture or tonnage band downgrades after a draft decision and data sharing. Enquiries on restrictions include many scope questions.

The microplastics proposal stood out in terms of questions received. Other topics include the PFAS proposal; tattoo inks; the lead in ammunition proposal; phthalates; nickel; CMRs in clothing, textile and footwear; diisocyanates; azocolourants and azodyes. For registration, the new and controversial topics were presented i.e. The UK's withdrawal from the EU and supply chain related topics (only representatives, re-import, legal entity changes), dossier updates including cease of manufacture and data sharing (12-year rule, unresponsive lead registrants).

In addition, Carmen KLAUSBRUCKNER noted the interlinkages of SCIP questions with REACH (e.g. definition of placing on the market, article definition, scope of Candidate List entries).

### Discussion

Representatives of several NHDs provided feedback on the (hot) queries received from their customers, with similar trends observed as, for example, queries on Brexit, substances in articles, restrictions and authorisation. Two NHDs stressed that their competent authorities are not responsible for answering SCIP questions directly.

Concerning the 12 year-rule, ECHA clarified that companies requesting data are directed to the lead registrant of the joint submission that owns the data.

Brexit-related questions received by one NHD were in relation to requirements for EU branches of (non-)EU legal entities to be established in the Community in the context of REACH, particularly regarding physical location (office) in the Member State in which the companies are based, as requirements for this appear to differ among Member States. ECHA cannot answer questions on national law and this issue would be a topic to be discussed in one of the upcoming REACH videoconferences.

## 2.4 SCIP database

Eoin BRENNAN (ECHA) introduced the SCIP database, the dissemination process and expected future improvements. There was also a brief demonstration of the database functionalities and features, as well as limitations in the data that has been submitted to ECHA.

The SCIP database[41] went public on 14 September 2021, with approximately 73 % of the data held by ECHA published corresponding to over four million articles notified.

[41] https://echa.europa.eu/scip-database

The speaker described in detail how the data is processed – starting with the data received by ECHA, the step in which confidential information is filtered and removed, through to publication on ECHA's website.

Concerning the quality of the data published, it was stressed that the responsibility is with the submitters. ECHA publishes the information as received without any corrections. In the background, data is updated continuously and 15-20 000 submissions are processed and published on the website every day.

An overview of the SCIP database portal was presented, showing that there were over six million articles notified. Two sample articles were presented; one well-structured example[42] (containing a full structure of the notified article), and one less optimal example[43] of a 'flat' notification, in which the structure of the article was omitted.

Future improvements[44] of the SCIP database are expected towards the end of the year, with publication of the over six million simplified SCIP notifications received. Additional improvements foreseen include a SCIP number search, identifier search improvements and other technical enhancements.

### Discussion

The Chair highlighted the impressive volume of data contained in the SCIP database, and the possibility of searching through over six million notifications in a fast and responsive way.

## Closing of the REACH Workshop

**The Chair** listed one action point as the outcome of the workshop. He thanked the presenters for their contribution and interesting presentations and all the participants for the lively discussions that had taken place. He invited participants to reply to the satisfaction survey, which will be sent after the meeting and closed the REACH Workshop.

[42] https://echa.europa.eu/factsheet/-/factsheet/4674795
[43] https://echa.europa.eu/factsheet/-/factsheet/4506455
[44] SCIP 2.0 on 24 November 2021. See a summary of changes on the Dissemination platform updates webpage at: https://echa.europa.eu/dissemination-platform-updates

# CLP Workshop

## Opening by the Chair

## 1. Updates from the European Commission and ECHA

### 1.1 Update from the Commission, including the CLP review

Anna SCHUSTER (European Commission, DG GROW) representing the CLP team (GROW, ENV), presented the main actions arising from the implementation of the Chemicals Strategy for Sustainability with a focus on the revision of the CLP Regulation. The presenter shortly briefed that as part of the strategy, a 'one substance, one assessment' approach for chemicals has been proposed, and the concept of safe and sustainable by design chemicals criteria has been defined.

The CLP revision will improve hazard identification by introducing new hazard classes, improve self-classifications and the poison centre notification system, simplify labelling requirements, introduce digital labelling, tackle online sales, etc.

With CLP the central piece of legislation for hazard classification in the EU, higher protection against most harmful chemicals can be achieved by adding the following new hazard classes: endocrine disruptors (based on the World Health Organization (WHO) definition for human health and environment); persistency, bioaccumulation and toxicity (PBTs + vPvBs based on the already existing REACH Regulation Annex XIII criteria); persistency, mobility and toxicity (PMTs + vPvMs – to be discussed and proposed at EU level and then brought to GHS[45]; immunotoxicity and neurotoxic (currently under STOT[46] and toxic for reproduction: assess the need for specific criteria); and terrestrial toxicity.

Anna SCHUSTER provided detailed information on the data collection procedural steps, and indicative timelines of upcoming actions, e.g. finalisation of the impact assessment by the end of March 2022; Commission's draft proposal of the CLP revision by mid-2022, then the proposal will be analysed by EU co-legislators, the Parliament and the Council. In 2023-2024, following the adoption of the revised CLP, the EU will present a proposal to the GHS in the working biennium regarding new elements to be added also in the GHS.

**Discussion**

Participants appreciated the useful and informative presentation, highlighting the ongoing activities under the Chemicals Strategy for Sustainability and the European Green Deal, and the activities to be expected in the coming period.

Referring to CARACAL 40, one participant mentioned that the Commission was not planning to extend the digital labelling options to any of the mandatory label elements that are now required by the CLP Regulation. Anna SCHUSTER confirmed that the Commission asked the contractor to look into the possibility to provide the option of shifting certain mandatory label elements to the digital domain; however, this would not be the pictograms, but, for example, precautionary-statements that overlap with the corresponding hazard-statements. Any elements moved to the digital domain would ideally need to be aligned with GHS, therefore, the Commission will be closely following any discussions in GHS on this topic.

Another participant referred to the lighters issue brought forward by the Irish helpdesk in October 2020 (see presentation Overlapping legislation on electronic lighters at HelpNet 15,

[45] Globally Harmonised System
[46] Specific Target Organ Toxicant

the CLP Workshop[47]), expressing their wish that the issue will be addressed in the CLP revision. The Commission confirmed that the subject of labelling small items such as lighters is being looked at.

## 1.2 CLP training sessions and videoconferences

Elena BIGI (ECHA) introduced the agenda of the first CLP training to be organised on 15 November 2021, with exercises on the classification of a mixture based on information given in a safety data sheet (SDS). The training is targeted to experts with some previous knowledge on the topic. A poll was run to understand the need and usefulness of organising training sessions and video conferences in the near future (see results in Annex IV).

## 1.3 Development and publication of the $TiO_2$ guide

Anisa KASARUHO (ECHA) presented the development of the titanium dioxide ($TiO_2$) guide, starting from the idea presented in October 2020 by the German helpdesk until the publication of the English version of the guide on 23 September 2021. In accordance with the 14th adaptation to technical and scientific progress (ATP), amendments were introduced in Annex VI, with an entry for $TiO_2$, and in Annex II, to provide specific requirements for the labelling of mixtures containing $TiO_2$.

At the CLP Workshop on 21 October 2020, the German helpdesk introduced the $TiO_2$ guide as published in 2020 by the Federal Institute for Occupational Safety and Health (BAuA). The guide introduced the German views on the interpretation of the $TiO_2$ classification and it was elaborated to help industry understand the classification and labelling of the substance. At the workshop, the German helpdesk asked HelpNet participants if they could share the German interpretation and recommendation.

After the workshop, the $TiO_2$ guide was translated into English by ECHA, and consulted with ECHA experts and the European Commission. In the next step, the guide was shared with HelpNet members through a written procedure. The feedback received from all parties was compiled into the final version of the guide, which was finally published in September 2021 on ECHA's website, under the HelpNet section[48].

Anisa KASARUHO presented the content of the guide, focusing on the classification of the powder form of $TiO_2$, the application of the EUH211[49] and EUH212[50] statements, as well as the use of EUH210 for mixtures not intended for the general public and not classified as hazardous.

### Discussion

Participants highlighted the importance of having the guide translated. Participants also commented on the scope of applicability of Article 25(6) of CLP to non-classified mixtures and highlighted that the legal wording of this provision could be clarified by the CLP revision. Anna SCHUSTER clarified that this issue is on the Commission's radar and might be addressed in the CLP revision.

On the question of whether $TiO_2$ queries should be replied by NHDs, ECHA suggested that new and unclear questions could be brought for discussion in the regular CLP videoconferences.

[47] https://echa.europa.eu/documents/10162/1627046/helpnet15_minutes_en.pdf/495d99b0-64db-d9ba-1789-5f51d4bfe198?t=1613474033373
[48] https://echa.europa.eu/about-us/partners-and-networks/helpnet/2020
[49] 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.'
[50] 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

# 2. Updates on CLP hot topics

## 2.1 Annex VIII: Relieving toll formulators from notification obligations

Nicolaj HEUER (German helpdesk), on behalf of Anja HACKMANN who could not attend the event, presented the toll formulator and notification obligations, a subject triggered by the queries received by the German helpdesk on Article 45[51] of the CLP Regulation.

Article 45 of CLP poses obligations on downstream users and importers to submit information (which is specified in Annex VIII) about hazardous mixtures placed on the market to appointed bodies and specifies the allowed uses of this information.

A toll formulator is a downstream user under CLP (and REACH) and therefore a duty holder under Article 45. They normally formulate mixtures on behalf of a third party, which places them on the market under their own company/brand name. Toll formulators provide the service to a customer which, if the customer does not change the mixture composition or perform downstream user activities (e.g. repackaging), acts as a distributor. As a distributor, they do not have direct obligations to notify under Article 45.

The ECHA guidance document[52] includes the possibility for the distributor to submit the notification on behalf of their supplier, therefore, relieving the toll formulators from their duty. The same document underlines that the toll formulator formally maintains their role as duty holder under Article 45, therefore, a contractual agreement would be needed between the parties to clarify the different obligations.

In this context, Nicolaj HEUER presented three scenarios in which the toll formulator of a mixture can make a submission, noting that the toll formulator's customer can create a new unique formula identifier (UFI) if desired which needs to be included in the toll formulator's submission to the Member States where it is placed on the market (and include it on the label) or make an own submission (as in the case of distributors) – bearing in mind that the toll formulator remains the duty holder under Article 45 of CLP.

### Discussion

The speaker asked if it is possible to release the toll formulator from the notification obligation and how enforcement could act. ECHA clarified that the possibility for the distributor to notify exists already (through contractual arrangements with the toll formulator and on its behalf) and it was accepted from the first version of the Guidance (even if it was further elaborated and clarified in the subsequent update).

This possibility may as well apply to other situations where the distributors have to notify themselves, for example, when the downstream users supplying the mixture do not intend to notify in the Member States where the distribution occurs, or they decide not to disclose business information. In all these cases and similar, such as for the notification by the toll formulator's customer, it is still clear that the duty holder under Article 45 remains the downstream user/supplier and, therefore, contractual agreements (outside Article 45 of CLP) would be needed.

ECHA reminded about the existence of the extended responsibility for all operators to comply with CLP obligations (including Article 45 and Annex VIII), under Article 4(10). ECHA also reminded that the consistency between the submitter's details in the submission and on the

[51] Member States must appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market.
[52] https://echa.europa.eu/guidance-documents/guidance-on-clp

label was removed with the first amendment of Annex VIII, one reason being exactly the situation with toll formulators.

Additionally, it was confirmed that the submission made by a distributor will not contain the supplier's details (due to technical limitations based on the decision not to allow submissions on behalf of a third party without them having access to the information submitted). ECHA questioned the need for enforcement authorities to get back to the supplier, since their identity will not be known.

The Chair proposed to park this matter until a discussion with Anja HACKMANN would be possible. If the German helpdesk wishes to follow-up the discussion on toll formulators, this should be done after the conclusion of the ongoing amendment of CLP, which assesses the need of whether to amend the definition of duty holder under Article 45. Subsequently, the discussion can be reopened in the context of a guidance update, if needed.

## 2.2 Supply of unpackaged hazardous mixtures to the general public

Nicolaj HEUER (German helpdesk) presented the concept of 'zero waste points of sale' in the context of increasing stores that sell unpackaged goods to consumers. Besides specialised shops, retail chains have also started to sell a wide range of products which are largely cosmetics, food, household chemicals, and during the COVID-19 pandemic also disinfectants.

Reusable packaging is a key concept, in which customers bring their own (dedicated) packaging, or the store makes dedicated or reusable packaging available.

The presenter mentioned the possible dangers of unlabelled or improper packaging, for example, for other people in the household. In addition, unused products may be (incorrectly) discarded because consumers may not be able to identify them after some time.

It was noted that unpacked sale does not occur if the customer leaves the point of sale with an adequately packaged and labelled product. The points for discussion raised by the presenter were: how can it be assured that the customer leaves the point of sale with an adequately packaged and labelled product and how can customers be assured that they can base their purchasing decision on all the labelling information they would normally have? More, how are enforcement authorities handling the situation in various Member States?

**Discussion**

Representatives of NHDs and industry shared similar experiences in their countries, supporting the idea of refill activities, but assuring that this is done appropriately. With an increasing number of stores, discussion on the best way forward is necessary. The Chair encouraged the other participants to also share their experiences and come up with some general recommendations after gathering information from various Member States.

## 2.3 Simplification and digitalisation of labels

The International Association for soaps, detergents & maintenance products (A.I.S.E.) represents the European manufacturers of cleaning, hygiene, and disinfectant products for household and professional uses.

Jan ROBINSON presented the activities of A.I.S.E targeted to the safe use of cleaning products, the consumer and legislation perspective, and the benefits of digitalisation.

A.I.S.E. is actively contributing to the Commission's initiative through its Better Regulation & Safe Use[53] (BRES) project, aiming to improve the effectiveness of safe use communication, to make sure that consumers notice the safety information, understand it, and act accordingly.

The objective of the project was to understand the consumer needs and concerns with labels and identify opportunities to simplify the content on the label according to the results. In an initial qualitative survey, 30 face-to-face interviews were conducted in three countries (Belgium, Spain and Poland) among buyers and users of household cleaning products, recruited from a mix of consumer profiles.

The results[54], built upon by a further A.I.S.E. quantitative survey conducted with 1 800 respondents (and subject of a scientific publication[55]) showed that consumers do not read the label much because of crowded content, unattractive labels, too much information and difficult to interpret, technical jargon.

Jan ROBINSON stressed that a simpler layout with only the necessary information on the package can be achieved by reassessing what needs to be on labels and what could be moved to public websites and provided illustrated examples of current labels and simplified ones, and also the differences between professional and consumer products.

As regards to digitalisation, the speaker highlighted the need to learn from the evaluation of IT solutions and market observations. It was noted that current labels do not succeed in conveying relevant safety information to consumers, and citizens have a growing interest to move to online information[56] irrespective of their age, with 80 % of the population interested in using digital technologies instead of on-pack information.

In her conclusions, Jan ROBINSON welcomed the Commission study on simplification of labelling and use of IT tools and the opportunities ahead:

- Aim for a clean, easy to read label that provides the important information.
- Remove ambiguity/inconsistencies from various regulations/overlaps.
- Maintain only the necessary information for safety.
- Make optimal use of icons/pictograms.
- Leverage digital space for the rest.

Industry is keen to help ensure this needed transition happens in a coherent way that will result in more relevant information to users, in close dialogue with all interested parties.

# 3. Helpdesk activities

## 3.1 Overview of ECHA Helpdesk enquiries

Anisa KASARUHO (ECHA) presented an overview of the ECHA Helpdesk CLP enquiries. The trends were covering the years 2018-2021 with a split between CLP and PCN. The topics proposed for discussion are the following:

1. Classification and labelling of $TiO_2$.
2. Classification and labelling of candles.

[53] https://www.aise.eu/our-activities/regulatory-context/classification-labelling/better-regulation-safe-use.aspx
[54] How often do you read instructions on detergents? Responses: 26 % never, 25 % sometimes, 19 % most of the time and 26 % always.
[55] Consumer studies - Investigating the effectiveness of simplified labels for safe use communication: The case of household detergents: https://onlinelibrary.wiley.com/doi/10.1111/ijcs.12662
[56] A.I.S.E. pan-European habits Survey 2020.

3. Label update following Brexit.
4. Other questions on labels: use of multiple languages in fold-out labels and QR code.
5. CLP FAQ development: 1456, 1726, 1727, 1808.

## 3.2 Break-out group discussions on most frequent enquiries

Erwin ANNYS, Elena BIGI and Anisa KASARUHO moderated three break-out groups.

Representatives of NHDs provided feedback on the enquires received from their customers:

- In general, similar queries as the ones received by ECHA.
- Article 45 and PCN.
- Annex VIII.
- $TiO_2$ guide.
- Candles.
- Labelling.
- Safety data sheets.
- Borderline between CLP and other legislation.
- Brexit, empty UFI.
- Nicotine.

Importance of support material available on ECHA's website:

- ECHA's website full of information.
- Support material was found to be sufficient.
- Webinars and workshops addressing PCN used to get knowledge on the topic.
- Subtitles of ECHA's videos would be helpful, but some could be translated in German and used by Austria, Germany, and Luxembourg.
- IT tools guide would not need a translation as notifications are done in English.
- Links still not working on ECHA's website, including the Q&A search function, difficult to find Q&As in a certain language.

Events organised by NHDs in their countries:

- Workshop on PCN.
- CLP Article 45 event.
- Safety data sheets – online event in December.
- PIC – online event.
- Campaign on internet sales.

Supporting documents issued by NHDs:

- Leaflets, guide documents.

Travelling

- Some NHDs do not have any limitations.

# Closing of the CLP Workshop

**The Chair** listed the action points as the outcome of the workshop. He thanked the presenters for their contributions and all participants for the interesting discussions. He invited the participants to reply to the satisfaction survey, which will be sent after the meeting and closed the CLP Workshop.

# BPR Workshop

## Opening by the Chair

## 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 implementation of the BPR, with a focus on the main findings of the report on the implementation of the BPR, follow-up on hot topics presented at the last HelpNet meeting and topics discussed in the competent authorities (CAs) meetings.

**Update on the COVID-19 impact on biocides**

Since the HelpNet meeting in October 2020, Member States (MSs) continued granting emergency permits under Article 55(1) of the BPR. Emergency permits were granted for:

- disinfectants (PTs 1, 2, 4), mostly for specific products and, in a few cases, generic derogations for products formulated according to WHO formulations.
- the use of a product for the treatment of aircraft fuel (PT 6).

Finding safe protective material and disinfectants in the context of a significant increase of suppliers was the major challenge during the COVID-19 pandemic. The Commission launched a Coordinated Activity on the Safety of Products (CASP) Corona2020[57] project to assess the risks to health and safety posed by this type of product. A total of 31 national, regional and local market surveillance authorities (MSAs) from 22 EU/EEA countries joined the project to test personal protective equipment (PPE) face masks, hand cleaners and disinfectants, and PPE gloves. The results and the final report of the project are available on the Commission's website.

**Report on the implementation of the BPR**[58]

The first report[59] on the implementation of the BPR, covering the period from September 2013 to December 2019, was published on 7 June 2021.

Concerning the functioning of the national helpdesks (NHDs), the main findings show that 75 % of the helpdesks replied to more than 200 enquiries/year and 50 % to more than 500 enquiries/year; the highest number of enquiries – of 2 000 enquiries/year – was reported by one country. Five reporting countries/helpdesks provided a breakdown for the type of enquiries received: with more than 90 % of enquiries related to biocidal products; about 8 % of enquiries related to treated articles, and around 2% of enquiries related to active substances. In addition, 15 helpdesks provided specific advice to SMEs, organising tailored events and providing additional guidance for SMEs.

Regarding active substances (ASs) in the Review Programme (RP), significant delays in the evaluation of applications by MSs and a sharp decrease in the number of assessment reports submitted by MSs after 2017 were reported. The main reasons for the delays were: lack of resources allocated in MSs, delay of applicants in submitting additional data, complex technical

[57] https://ec.europa.eu/safety-gate/#/screen/pages/casp2020Corona
[58] Commission Report and Staff Working Document available at:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0287
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021SC0128
[59] Legal basis: Article 65(3) and 65(4) of the BPR.

questions on dossiers that need to be resolved first, development of technical guidance and the adoption of ED criteria.

Ligia NEGULICI reported on the number of AS/PT combinations adopted since the start of the RP, the existing ASs outside the RP, new ASs (i.e. not on the EU market before 14 May 2000 for biocidal purposes), and the number of Union-wide authorisations (UA) of biocidal products introduced by the BPR, with the first UA granted in 2018.

Regarding national authorisation and mutual recognition of biocidal products, in most MSs, the majority of the products authorised on the market were authorised following mutual recognition procedures. Significant delays affected ~63 % of procedures for mutual recognition in sequence and ~72 % of procedures for mutual recognition in parallel.

The direct consequence of the limited progress with the RP is that most of the products currently present on the market (several tens of thousands) are being made available under national transitional rules and not assessed in line with criteria set out in the BPR.

Concerning treated articles, according to data reported by seven MSs, relatively few articles treated with non-allowed ASs were revealed by controls conducted between 2013 and 2018; higher incompliance rates were registered for labelling obligations (more than 30 % of articles checked); in many cases, the suppliers of treated articles were not aware of the requirements under the BPR. The main findings of the harmonised enforcement project BEF-1, which was carried out in 2019, are detailed below:

- 1 187 companies inspected.
- 1 844 TAs checked (70 % articles, 30 % mixtures).
- 73 % of TAs checked were manufactured in EU.
- presence of labelling: very high compliance (>90 %), though 50 % of checked articles were incompliant – missing info on AS and biocidal properties and 23 % of checked mixtures showed incompliances (CLP already applied).

The representative of the Commission highlighted that despite positive findings – for instance, the BPR provisions being fully operational, the progress with the RP is alarmingly slow, substantial delays occur for both AS approval and product authorisation procedures, with very limited innovation on new ASs.

The completion of the RP is crucial for the achievement of the BPR objectives. The regulatory system set out in the BPR cannot function properly unless MSs take measures to ensure that their authorities have necessary resources and qualified staff to fulfil their obligations under the BPR.

As a follow-up action, Commissioner Kyriakides sent letters to ministers responsible for biocides asking them to review the situation in their country, take appropriate measures to ensure that competent authorities can execute their role under the BPR, and assess whether their national fee systems needs to be improved. Moreover, discussion in the meeting of EU environment ministers (Environment Council) took place on 6 October and discussion in the Health Council is scheduled on 7 December 2021.

**Same biocidal products: mutual recognition and renewal**

Discussions in the CA meeting took place on whether 1) same BPs authorised according to Regulation (EU) 414/2013 (Same BP Regulation) can be subject to: mutual recognition and renewal; and 2) if mutual recognition is restricted only to authorisations granted through national authorisation (full application of Chapter VI of BPR)? The Commission's view is that

under the relevant provisions of the BPR there is no legal reason to distinguish national authorisation of same BPs from other national authorisations (Article 3(1)). Hence, any national authorisation (including SBP) can be recognised in other MSs in accordance with Article 32(1).

The renewal of same BPs authorisation is not mentioned in the BPR or in the Same BP Regulation, However, the Guidance on the BPR states: *'The authorisation of same BP will have a different authorisation number and may be changed, renewed or cancelled independently of authorisation related to the reference product.'* The following provisions apply: the renewal of a national SBP authorisation is governed by Article 31 of the BPR, and the renewal of a Union SBP authorisation is governed by Articles 45 and 46 of the BPR. Renewal of an SBP authorisation based on a reference product authorised through mutual recognition falls under the Regulation (EU) No 492/2014 on renewals of authorisations of BPs subject to mutual recognition ('the Renewal Regulation').

**Renewal of anticoagulant rodenticides – update**

Agreement was reached at the CA meeting of June 2021: MSs will grant a renewal of the authorisation/extension of authorisation (as set out in Article 31(7)) until 1 July 2024. This will enable MSs to consider in the renewal evaluation the agreement regarding the dermal absorption value and the outcome of the EU comparative assessment[60] that is expected to be finalised by the end of 2022.

At the same time, the procedures of the BPR and of Regulation (EU) 492/2014 (Renewal Regulation) continue to apply and applications for renewal need to be submitted according to the deadlines (at the latest 550 days before the authorisation (initial) expiry date).

**Regulation on explosive precursors**

The new Regulation (EU) 2019/1148[61] on the marketing and use of explosives precursors imposes new obligations on economic operators, as well as on members of the general public.

As under the previous regulation, the substances listed in Annex I of the new regulation (among which is hydrogen peroxide) are considered restricted explosive precursors and shall not be made available to or introduced, possessed, or used by the members of the general public if they are contained above concentrations specified in the regulation. For hydrogen peroxide, this is 12 %. However, authorised biocidal products for use by the general public have concentrations below 12 %. A new element introduced by this regulation is the second category of substances, namely regulated explosive precursors, covering substances included in two annexes to the regulation. One of them is again hydrogen peroxide in concentrations above 1 % w/w. For both types of precursors, reporting obligations are in place. However, this reporting is different from the reporting under Article 65 of the BPR.

**Early review of active substance approval – update**

The early review was initiated in February 2020 for iodine, PVP-iodine, zineb. In May 2021, a request for opinion was transmitted to ECHA, on whether the active substances are considered to have ED properties (with respect to humans and/or non-target organisms). Applicants were given the opportunity to submit comments and the information received was published on the website[62].

[60] Targeted consultation to collect information will be organised by ECHA in 2022.
[61] https://eur-lex.europa.eu/legal-content/FI/TXT/?uri=celex:32019R1148
[62] https://ec.europa.eu/health/biocides/active_substances/review_approval_en

## 1.2 Enforcement activities of the Forum BPR Subgroup (closed session)

## 1.3 First judgment on approval decisions under the BPR

Tomas ZBIHLEJ (ECHA) presented the first judgment on two cases related to the non-approval of the substance PHMB (product types (PTs) 1, 5, 6) and the conditional approval for PTs 2 and 4. He explained the background of the cases, the pleas, final analyse and clarified the judgment[63] in the context of the applicant's right to be heard. The judgment refers to the procedure of the active substance (AS) approval process and it clarifies the relation with CLP. It also indicates that when in the process new data can still be submitted by the applicant.

The applicants were the Laboratoire Pareva manufacturer of PHMB (1415; 4,7)[64] ('Pareva's PHMB') used for biocidal purposes and Biontech3D manufacturer of biocidal products containing Pareva's PHMB.

ECHA's Biocidal Products Committee[65] (BPC) had expressed concerns and decided not to recommend the approval of PHMB (1415; 4.7)[66] for PTs 1, 5 and 6, because its persistence would lead to unacceptable risks to the environment and its teratogenic properties posed a risk to human health. The BPC did recommend approving the use of PHMB for PTs 2 and 4, subject to specifications and conditions. The BPC opinion on the non-approval of the active substance PHMB (1415; 4.7) in PT 5 was adopted on 4 October 2017 and published on ECHA's website[67].

The Commission followed the opinion of the BPC.

Laboratoire Pareva sought annulment of the Commission Implementing Decisions of 20 April 2018 not approving PHMB (1415; 4.7) – as an existing AS for use in BPs of PTs 1, 5 and 6 (Case T-337/18) – and for use in BPs of PTs 2 and 4 (Case T-347/18), saying that the Commission made procedural errors when processing the assessment report for the substance.

Other alleged failures were appealed against the eCA procedures for the harmonised classification of the substance, the BPC's assessments, failure to take part in consultation with the PBT expert group, failure to admit new studies and documents submitted by Pareva – all rejected by the Court.

The Court noted that the CLP classification and BPR AS approval procedures are independent and a failure to submit a classification proposal as part of an assessment of a BPR application for AS approval does not vitiate a decision on the application.

With regard to an alleged infringement of the right to be heard, the Court held that acts of general application, as in this case, do not require the participation of the persons affected unless there is a specific legal provision conferring a procedural right.

## 2. Updates from the Biocides units

[63] Judgment of the General Court: https://curia.europa.eu/juris/document/document.jsf?text=&docid=246001&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=8692079

[64] Common name: polyhexamethylene biguanide hydrochloride with a mean number average molecular weight (Mn) of 1415 and a mean polydispersity (PDI) of 4.7).
Chemical name: CoPoly(bisiminoimidocarbonyl, hexamethylene hydrochloride),(iminoimidocarbonyl, hexamethylene hydrochloride)

[65] https://echa.europa.eu/documents/10162/37b85a8b-fb54-4207-6e1c-cd3b3841cdf3

[66] Since the substance was classified as a category 1B skin sensitiser, a category 2 carcinogen, a specific target organ toxicant by repeated exposure by inhalation, and a toxicant to aquatic life (category 1).

[67] https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

## 2.1 BPR support material and guidance

Claudio PUTZU (ECHA) provided an update on the development of the BPR support material, since the previous meeting in October 2020, and on work planned for the coming years.

Regarding guidance updates, the speaker referred to the following guidance under revision and estimated publication dates:

- Risk to pollinators from biocides (Q4/2022).
- Working Group recommendations on in-situ substances (Q2/2022).
- Human Health volume III, part A: Information Requirements (Q1/222).
- EFSA and ECHA guide on residues of active substances in drinking water (Q3/2023).
- Guidance on efficacy revisions for PT19 (Q4/2021).

In addition, ECHA published a document[68] aiming to assist companies interested in applying for technical equivalence for alternative sources of 'active chlorine released from hypochlorous acid'.

To support the Member State competent authorities (MSCAs) in assessing the confidentiality of the information in the application dossiers for approval of an active substance (AS) or the authorisation of a biocidal product, ECHA developed new Guidelines on confidentiality claims[69]. Although the document is mainly targeted at MSCAs, it is also relevant for companies making applications under the BPR.

More information on the ongoing projects and foreseen additional priorities are available in the document available in CIRCABC[70], the update[71] presented in the 'biocides' stand during the ECHA Safer Chemicals Conference, and the overview of the interim documents published in connection to ECHA's guidance consultations[72].

Claudio PUTZU mentioned the changes in the templates of the Product Assessment Report[73] (PAR), Competent Assessment Report[74] (CAR) and the updates of the BPR web pages concerning opinions on Union Authorisation[75]. Information on the new PAR template[76] was also presented at the BPR stand at ECHA's conference in October 2021.

Finally, the speaker informed the participants of future improvements in the pipeline including

[68] Active chlorine released from hypochlorous acid: Advice on information requirements for technical equivalence applications under Article 54 of the BPR: https://echa.europa.eu/documents/10162/17234/hypochlorous_acid_advice_applicants_en.pdf/1d0a92cb-49aa-8154-1532-571627435681

[69] https://echa.europa.eu/documents/10162/992289/guidelines_assess_bpr_conf_claims_en.pdf/#page=2&zoom=100,92,145

[70] Guidance priorities: Path: /CircaBC/SANTE/BPR - Public/Library/CA meetings/93rd CA meeting September 2021/CA-Sept21-Doc.7.6. -ECHA guidance priorities.docx
Browse url: https://circabc.europa.eu/w/browse/e6d18e72-13cc-4046-876d-255803fb6913

[71] Update on ECHA's current guidance activities: https://echa.europa.eu/documents/10162/10543934/biocides_update_on_guidance_20211006_en.pdf/d54ca810-91cd-986a-ab7c-5369e5eebb73?t=1633513389975

[72] Ongoing guidance consultations: https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-bpr

[73] https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

[74] https://echa.europa.eu/it/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities

[75] https://echa.europa.eu/it/opinions-on-union-authorisation/bpc

[76] Revised Product Assessment Report (PAR) templates presentation: https://echa.europa.eu/documents/10162/10543934/biocides_revised_product_assessment_templates_20211006_en.pdf/bc4c9cb4-c598-3646-c4c8-9ca3a5425530?t=1633513389597

the publication of ECHA opinions on the classifications of changes under the Change Regulation. Changes on AS factsheets were also mentioned. Indeed, the current 'Assessments' tab will be renamed 'history details and assessments' and clarifications concerning the use of the case-type 'Amendment of active substance - (AS-AAT)' will be introduced. This type of amendment is linked to changes of a more administrative nature e.g. the need to update documents or approval timelines that do not require an assessment. Hence, they need to be distinguished from the cases where the evaluation is needed e.g. under Article 15 of the BPR.

**Discussion**

Concerning envisaged changes to the ECHA website, one of the participants highlighted that external users may have difficulties to find some information on the ECHA website; particularly for the *Guidance on confidentiality* and the *Guidelines on the technical equivalence for active chlorine*, the current location not being intuitive. To stay updated on new developments, NHDs can subscribe to the ECHA Weekly bulletin where new publications are announced.

It was also highlighted that it would be beneficial to include in the AS factsheet the information on re-defined substances and the link between original identity and the identity in which it was re-defined to allow the traceability of both identities. ECHA noted the comment and sees the possible advantages of this approach, however, from the technical point of view it would be very challenging as this would probably involve changes in R4BP 3 and how the system is designed. ECHA also clarified that this information is at the moment available on the Article 95 list[77].

## 2.2 Revising the Working Group recommendation for *in situ* generated substances

Eva VALKOVICOVA (ECHA) presented the upcoming revision of the current Working Group Recommendation on *in situ* generated actives substances (ASs) in the context of ongoing discussions in the CA meetings. The speaker explained the *in situ* generation process and gave examples of biocidal product (BP) case types and an overview of upcoming changes.

The speaker recapped the definitions for '*in situ* generated active substance', '*in situ* generation', 'precursor', and 'device', the latter being the equipment or technology used in the *in situ* generation process.

Eva VALKOVICOVA highlighted that the scientific recommendation made by the Working Group is focusing on information requirements mainly for the purpose of the approval of *in situ* generated substances and will also include information requirements for BPs of *in situ* generated substances. The information is useful for the evaluating competent authorities (eCA) and to the applicants.

The current recommendation of the Working Group was developed and agreed in 2016 and 2017, by the four BPC working groups, and is available on ECHA's website[78]. The need to amend the current recommendation was triggered by discussions in the CA meetings (91st CA meeting in March 2021)[79] addressing the principles for the management of product

[77] https://echa.europa.eu/information-on-chemicals/active-substance-suppliers
[78] *In situ* generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors: https://echa.europa.eu/documents/10162/17234/situ_as_precursors_wg_recommendation_+2017_en.pdf/0c6aee50-5c29-bccc-3836-bb033a015144
[79] CA meetings in CIRCABC: Path: /CircaBC/SANTE/BPR - Public/Library/CA meetings

authorisation where the active substance is generated *in situ*.

For the revision of the recommendations, ECHA experts, volunteering Member States, established a task group responsible to draft new parts for biocidal products and to re-draft the active substance part based on experience and on the CA agreement. The updated recommendations shall be agreed by Q2 in 2022.

The following case types of BPs were introduced:

- Case-type 1: the *in situ* BPs involve an *in situ* IGS (*in situ* generation system) based on mixing of two or more [formulations containing the] precursors. For example: paracetic acid from tetraacetylethylenediamine (TAED) + sodium percarbonate or sodium chlorite (P1)+ acid (P2) to generate chlorine dioxide.

- Case-type 2: the *in situ* BPs involve an IGS based on one or more [formulations containing the] precursors. For example: active chlorine from sodium chlorine by electrolyses precursors used in a device.

- Case type 3 – free radicals – still under discussion. For example: TiO2 coating generating free radicals.

- Case type 4 – might be revised (to include free radicals) based on the outcome of the case type 3 discussion. For example: active chlorine from table salt by electrolyses, or active chlorine from sea water by electrolyses or ozone from ambient air.

The *in situ* generation is a very complex process from the scientific and regulatory point of view. As the recommendations are addressing only the 'scientific' questions, they should always be read together with the CA document addressing the regulatory context.

**Discussion**

ECHA clarified the difference between case-types 2 and 4: in case-type 4, the table salt is not marketed as a BP. For the moment in cases 2 and 4, the applicant can decide whether the precursor is a BP. This is, however, under consultation between the competent authorities.

Regarding the question on devices[80] included in the product authorisation, ECHA clarified that a device used in the *in situ* generation process has to be described in field 'Application method(s)' that is available in the tables describing the relevant uses in section 4 of the summary of the product characteristics (SPC). The description should indicate the relevant specifications or standards of the device that will be covered by the authorisation. The device as such will not be authorised.

## 2.1 Progress of the active substance action plan

Carmen ESTEVAN MARTINEZ (ECHA) presented the state of play of the Review Programme, and the ongoing activities within the Action Plan.

Browse url: https://circabc.europa.eu/w/browse/661e8fca-9353-47da-a031-c1341d6aa335
CA-July19-Doc.4.1-Final amended by CA-Dec20-Doc.4.14 and CA-March21-Doc4.10.

[80] The 'device' designates the equipment or technology used in the in situ generation process. This device may enable the users to set the values of the parameters that may affect the chemical reactions and the composition of the AS generated *in situ*.

In February 2020, at the 87th CA meeting, the active substance action plan (ASAP)[81] agreed to identify ways to accelerate the evaluation of substances in the Review Programme (RP). With a few years left before the deadline, only 50 % of the substance/product type (AS/PT) combinations[82] were under assessment for their first approval.

As a result of the delays in the active substance approval process, there is no level playing field for companies in the biocides sector and some biocidal products with possible unacceptable risks available on the market are not managed. To address these issues, a survey was conducted in 2018 to collect information from Member State competent authorities (MSCAs) on the status of the RP dossiers. A workshop was organised in 2019 on how to improve the substance approval process, with a focus on the substances covered by the Review Programme Regulation. Representatives of MSCAs, accredited stakeholders (ASOs) and the European Commission participated in the workshop (see agenda item 3.4 Update on the active substance workshop programme in the minutes of HelpNet 14[83]).

Five main areas were identified as blocking factors and actions were elaborated and published on ECHA's website[84]. The ongoing actions for ECHA, competent authorities and the Commission were set to contribute to progressively unblocking evaluations, moving forward the approval of ASs:

Action 1. Prioritisation of dossiers:

- Agreement on priorities on finalisation of assessments and intensified interaction via the ECHA national contact point and joint planning of the finalisation of AS assessments until 2024 are addressed. The progress made is recorded and made available in S-CIRCABC[85].

Action 2. Support to eCAs:

- Substance identity issues often lead to delays in the evaluation of active substances (e.g. need for redefinition, further discussion at WGs). MSs to check and ECHA to confirm whether the substance identity is correct and consistent with REACH guidance. Document agreed at the September 2021 CA meeting available in S-CIRCABC[86].

- Capacity building in eCAs: a workshop is foreseen together with EFSA, aimed at learning from the experience on substances already assessed, especially on data requests and strategy for the requirements. The workshop on ENV ED assessment is expected to take place during Q4 2021. Also, ECHA started to work on guidance for applicants and MSs to support the analysis of the alternatives. The guidance will also include templates for MSs and applicants. In addition, a first discussion on the table of contents and note to the guidance took place at the BPC October meeting.

---

[81] https://circabc.europa.eu/d/a/workspace/SpacesStore/802be742-3fcf-4011-9558-83ab2006a950/CA-Feb20-Doc.5.2 - Final - AS Action Plan.docx
[82] Table with information per active substance/product-type combination: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances
[83] https://echa.europa.eu/about-us/partners-and-networks/helpnet/2019
[84] https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances
[85] Progress of AS evaluations as regards the determination of ED properties:
Path: /CircaBC/SANTE/BPR - Public/Library/CA meetings/90th CA meeting December 2020/CA-Dec20-Doc.5.1 - Progress of AS evaluations as regards the determination of ED properties.docx
Browse url: https://circabc.europa.eu/w/browse/ece65a2e-646c-462f-9c63-00dad236eefd
[86] Verification campaign for a correct identification of ASs:
Path: /CircaBC/SANTE/BPR - Public/Library/CA meetings/93rd CA meeting September 2021/CA-Sept21-Doc.5.6 - Campaign Substance Identification.docx
Browse url: https://circabc.europa.eu/w/browse/1f4133e3-e0c3-47e4-b206-d4c29c129670

Action 3. Streamline the peer review:

- Improving the effectiveness of WGs: several actions have been proposed to the BPC and WGs to improve the efficiency of the meetings; the proposals were targeting specific aspects of the opinion-forming phase (e.g. follow-ups of the WGs and amendment of timelines for the different steps of the peer-review).

Action 4. Reduction of complexity:

- Focused assessment of safety and efficacy (FAST project) intending to elaborate on best practice for a focused assessment of safety and efficacy, including the reduction of uses to be assessed at approval level. The project aims to reduce the complexity and speed up both evaluation and peer review phases.

Action 5. Harmonised assessment of confidentiality claims:

- Guidelines[87] were published to support MSCAs in assessing confidentiality claims in the application for approval of an AS or the authorisation of a BP under preparation.

Signs of acceleration appeared at the end of 2020, when the number of draft CARs entering peer-review increased from 8 in 2020 to 18 in 2021; and the number of opinions on AS increased from 15 in 2020 to 20 (estimate) in 2021. Regular updates on the AP progress are given in the CAs meetings and published in S-CIRCABC[88].

Estimates made by the MSCAs on the finalisation of the AS dossiers, showed that the RP will not meet the 2024 deadline, but most of the cases would be finalised by the end of 2024. An overview of the plan[89] was presented in the CA meeting in September 2021.

The aggregated figures from the MSs plan show a very rapid increase in 2022 of the number of assessment reports on AS entering the opinion-forming phase. A peak of up to 65 AS assessment reports, corresponding to 152 AS/PT combinations and related BPC opinions are foreseen in 2022.

## Discussion

The topic of re-definition of the substances was raised again in the context of possible withdrawal of the original identity from the RP. ECHA explained the main steps of the process including publishing an open invitation to take over the role of the participant in the RP and highlighting that the original substance identity is not automatically removed from the RP following its re-definition. It remains in the RP until the final Commission decision. More information on the AS re-definition was provided in 3.1.

One of the participants asked if the workshop on the assessment of the endocrine-disrupting properties with respect to non-target organisms will be also available for the stakeholders.

---

[87] Guidelines for assessing the confidentiality of the information contained in the Competent Assessment Report (CAR) and Product Assessment Report (PAR): https://echa.europa.eu/documents/10162/992289/guidelines_assess_bpr_conf_claims_en.pdf/3c579364-5a0b-b098-06bf-3323f5b8a496?t=1632295766830

[88] Update on ASAP - progress report (June – September 2021):
Path: /CircaBC/SANTE/BPR - Public/Library/CA meetings/93rd CA meeting September 2021/CA-Sept21-Doc.5.5- ASAP report.docx
Browse url: https://circabc.europa.eu/w/browse/5d306db6-8301-4c87-bada-f2e78afe945c

[89] Update of MSs forecast for the submission of AS and UA assessments in 2021 – 2024:
Path: /CircaBC/SANTE/BPR - Public/Library/CA meetings/93rd CA meeting September 2021/CA-Sept21-Doc.7.8 - AS and UA ECHA 2021-2024_rev1.pdf
Browse url: https://circabc.europa.eu/w/browse/b2ff761f-77e2-44b4-bcf8-5fb0b4a4eae6

ECHA explained that the workshop is basing on the experience of the participants gathered from the assessment of other cases and it is aimed to establish the strategy for the information requirements and possible deviations from the guidance document. It will be also covering the example of specific dossiers. Therefore, it's targeted on the participation of Member States and it would be difficult to involve the stakeholders in the discussions.

# 3. Helpdesk activities

## 3.1 Overview of the ECHA Helpdesk hot topics

Malgorzata SZKLAREK (ECHA) gave an update on ECHA Helpdesk BPR hot topics.

She presented statistics related to the BPR questions received by the ECHA Helpdesk in 2020 and 2021. In 2021, around 20 % of all the questions were queries related to the BPR (in comparison, in 2020 around 33 %). Also, 2021 was more stable and a more predictable year as regards the number of incoming questions per month, whereas in 2020 due to COVID-19 a clear peak between March-August was observed.

In 2020, ECHA got more than 1 600 BPR questions of which 42 % were COVID-19 related, while by the end of October 2021, ECHA received around 850 queries, out of which only 7 % were related to the pandemic.

By the end of 2021, the expected number of queries is 950, which is about 650 questions less than in the previous year, but still about 200 queries more than in pre-COVID years. It clearly shows that the interest in biocidal products created by COVID-19 is still lasting.

The speaker explained the development of ECHA's COVID-19 Q&As[90] and how they are used to quickly respond to questions related to making available disinfectants on the market.

Another part of the presentation was addressing the most popular topics in 2021 asked by ECHA customers. General questions related to different processes under the BPR (placing on the market, granting authorisations, including changes) were the most popular, followed by enquiries on the active substance approval and the regulatory status of different active substances.

Malgorzata SZKLAREK presented examples of the questions that may also be relevant for national helpdesks (NHDs):

- same biocidal product of same biocidal product and
- the Article 95 obligation for undefined precursors using as an example 'chlorine dioxide, generated from sodium chlorite by acidification'.

In both cases, ECHA consulted the European Commission, and it was agreed that a same biocidal product can be used as related reference product for authorisation of a new same biocidal product. For Article 95, this obligation applies if the undefined precursors are supplied with the intention to generate an active substance. However, if undefined precursors are placed on the market as commodity chemicals (e.g. sulfuric acid and similar acids used as second precursor for the generation of chlorine dioxide) and no biocidal claim is made, the Article 95 obligation does not apply.

As some questions received by ECHA this year were related to the re-definition of active substances, the process has been described in detail using as an example 'silver chloride'

[90] https://echa.europa.eu/documents/10162/28801697/q_a_covid_disinfectants_en.pdf/f380496a-d61a-1ff1-ee78-12d302c5d520

(redefined from a reaction mass of titanium dioxide and silver chloride).

Malgorzata SZKLAREK also presented real-life examples of the questions related to the delays at national level. One example was linked to the delay in active substance evaluation, another concerned the MSCAs dealing with the administrative change application. The last example was related to granting national authorisations for biocidal product families.

It was explained how ECHA responded to these questions and it was highlighted that as customers tend to complain about low responsiveness of evaluating competent authorities (CAs), it is extremely important for competent authorities to inform the applicants regularly on the status of their applications and to respond to such questions – also when no progress has been made.

**Discussion**

In relation to the active substance re-definition, one of the participants asked if there is a list of original and re-defined substance identities. ECHA explained that there is no such list at the moment, however, this information is available at the Article 95 list and it can be retrieved from the ECHA's open invitations for notifications[91] and R4BP 3.

ECHA noted all the questions and comments on this topic and will further reflect internally on how this information could be presented in the way that would be easier to find.

## 3.2 Sharing experiences – open discussion

Malgorzata SZKLAREK (ECHA) introduced the questions related to COVID-19 as an opening point for the discussion:

- What was most challenging when dealing with COVID-questions?
- What was the strategy of your helpdesk in dealing with COVID-related questions?
- How did teleworking/remote working influence the way of working at your helpdesk?
- Have you observed any drop in the number of COVID enquiries received in 2021 compared to 2020?

National helpdesks (NHDs) were invited to share their experience and observations on trends related to the COVID-19 related questions.

As the most challenging, participants indicated:

- the number of questions arriving in a very short time, although they were not complex;
- the fact that a lot of new companies, with very limited knowledge about the BPR and therefore requiring more support, wanted to enter the market; and
- the time-limit (180 days) for Article 55(1) derogations and the fact that during this period it was not feasible to grant regular authorisation for such products.

Regarding the strategy in dealing with COVID-19 questions, some participants reported development of Q&As or templates used in standard replies e.g. for ethanol, newsletter, phone support and additional human resources delegated temporarily to answer COVID questions.

Considering the teleworking, attendees stated that apart from some minor initial technical problems that some of them faced, it was not causing major problems and their experience is very positive.

[91] https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/successful-declarations-of-interest

As regards the amount of enquires related to COVID-19, NHDs noted similar trends as ECHA.

The total number of questions received by NHDs in 2020 was usually 4-5 times higher than in 2019. Although the COVID-19 questions were not so popular in 2021 (one participant reported a drop from around 600 questions in 2020 to around 100 in 2021), NHDs received significantly more BPR questions than before the pandemic, which indicates a rise of public awareness as regards biocidal products and the role of disinfectants in fighting the pandemic.

Participants had the opportunity to answer some poll questions[92]. The results are available in Annex IV.

## Closing the BPR Workshop

**The Chair** listed the action points as the outcome of the workshop and thanked participants for the interesting discussions. He invited the participants to reply to the satisfaction survey which will be sent after the meeting and closed the BPR Workshop.

[92] From poll 6 to poll 10.

# Annex I – Agendas

## Tuesday, 2 November 2021

### 16th HelpNet Steering Group meeting

1. **Opening the Steering Group meeting** (11:00-11:20)
   1.1 Opening by the Chair of the HelpNet
   1.2 HelpNet 15 - follow-up of action points
   1.3 Approval of the HelpNet 16 draft agenda
2. **Updates from the HelpNet Secretariat** (11:20-12:30)
   2.1 Upcoming annual survey on helpdesk activities - tips (ECHA, Viorica NAGHY)
   2.2 Report on unsolved/timed-out questions (ECHA, Roxana BROASCA)
   2.3 HelpNet update on new ways of working (ECHA, Elena BIGI)
   2.4 Role of HelpNet – new ways of working and how to increase harmonisation/ cooperation (ECHA, Elena BIGI)
3. **Updates from ECHA** (13:30-15:05)
   3.1 Communication activities (ECHA, Johanna SALOMAA VALKAMO)
   3.2 Forum activities (ECHA, Maciej BARANSKI)
   3.3 Feedback from ECHA on Chemicals Strategy for Sustainability (ECHA, Erwin ANNYS)
   3.4 Report on the operation of REACH and CLP - Article 117 REACH, Article 46 CLP (ECHA, Catherine CORNU)
4. **Collaboration activities** (15:20-15:45) [Closed session]

**Closing the Steering Group meeting** (15:45-16:00)

**Virtual social event: have a coffee with us** (16:00-16:30)

## Wednesday, 3 November 2021

### REACH Workshop

**Opening by the Chair** 10'

1. **Updates from the European Commission and ECHA** (11:10-12:45)
   1.1 Update from the Commission, including the REACH review (DG GROW, Riccardo ZORGNO)
   1.2 Guidance on registration (ECHA, Alexis QUINTANA-SAINZ)
   1.3 Unclaimed NONS project (ECHA, Maria Jose BELMONTE SANCHEZ)
   1.4 Latest update from evaluation (ECHA, Katrin HALLING)
2. **Updates from ECHA** (13:45-15:10)
   2.1 Restrictions update (ECHA, Augusto DI BASTIANO)
   2.2 Persistent organic pollutants (ECHA, Ignacio GONZALEZ RODRIGUEZ)
   2.3 Overview of the ECHA helpdesk hot topics (ECHA, Carmen KLAUSBRUCKNER)
   2.4 SCIP data base (ECHA, Eoin BRENNAN)

**Closing the REACH Workshop** (15:15-15:30)

## Thursday, 4 November 2021

### CLP Workshop

**Opening by the Chair** 10'

1. **Updates from the European Commission and ECHA** (11:10-12:20)
   1.1 Update from the Commission, including the CLP review (GROW, Anna SCHUSTER)
   1.2 CLP training sessions and videoconferences (ECHA and NHDs)
   1.3 Development and publication of the $TiO_2$ guide (ECHA, Anisa KASARUHO)
2. **Updates on CLP hot topics** (13:20-14:20)
   2.1 Annex VIII : Relieving toll formulators from notification obligations (German helpdesk, Nicolaj HEUER)
   2.2 Supply of unpackaged hazardous mixtures to the general public (German helpdesk, Nicolaj HEUER)
   2.3 Simplification and digitalisation of labels (A.I.S.E, Jan ROBINSON)
3. **Helpdesk activities** (14:35-15:20)
   3.1 Overview of the ECHA Helpdesk enquiries (ECHA, Anisa KASARUHO)
   3.2 Break-out group discussions on most frequent enquiries
   3.3 Conclusions of the break-out groups (15:40-16:10)

**Closing the CLP Workshop** (16:10-16:30)

## Friday, 5 November 2021

## BPR Workshop

**Opening by the Chair** 10'

**1. Updates from the European Commission and ECHA** (11:10-12:30)

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

1.2 Enforcement activities of the Forum BPR Subgroup (ECHA, Nicola TECCE) [closed session]

1.3 First judgment on approval decisions under the BPR (ECHA, Tomas ZBIHLEJ)

**2. Updates from the Biocides units** (13:30-14:30)

2.1 BPR support material and guidance (ECHA, Claudio PUTZU)

2.2 Revising the Working Group recommendation for *in situ* generated substances (ECHA, Eva VALKOVICOVA)

2.3 Progress of the active substance action plan (ECHA, Carmen ESTEVAN MARTINEZ)

**3. Helpdesks activities** (14:45-15:45)

3.1 Overview of the ECHA Helpdesk hot topics (ECHA, Malgorzata SZKLAREK)

3.2 Sharing experiences – open discussion (e.g. COVID-19, challenges under the BPR from a national helpdesk`s perspective)

**Closing the BPR Workshop** (15:45-16:00)

**End of the HelpNet 16 events**

## Annex II – List of participants

| Country | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| Austria | Barbara WETZER | X | | X | X |
| | Erich NEUWIRTH | | | X | X |
| | Jérôme COLSON | | X | | |
| | Hemma SAMPL | X | | | |
| Belgium | Daphné HOYAUX | | | | X |
| | Kristof CLAES | X | X | X | |
| Bulgaria | Margarita GAIGUROVA | X | X | X | |
| Croatia | Zdravko LOVRIĆ | X | X | X | X |
| | Irena Zorica JEŽIĆ VIDOVIĆ | X | | X | X |
| Cyprus | Andreas HADJIGEORGIOU | | X | | |
| | Maria ORPHANOU | X | | X | X |
| | Maria PALEOMILITOU | X | | X | |
| Czech Republic | Jarmila SLÁDKOVÁ | X | | X | X |
| | Jan KOLAR | X | | | |
| Denmark | Lone KAERGAARD | | X | | |
| | Ditte PALUDAN | X | | X | |
| | Helle HUSUM | | X | | |
| | Maria THESTRUP JENSEN | X | X | | |
| | Toke THOMSEN | X | | | |
| Estonia | Anna AMELKINA | X | | | X |
| | Aigi LAHE | X | | X | X |
| | Riina LAHNE | X | X | | |
| Finland | Hannu MATTILA | X | X | | |
| | Mervi ASSMANN | X | X | | X |
| | Antti NIEMINEN | | | X | X |
| | Pauli KÄRKKÄINEN | X | | X | |
| | Sari TUHKUNEN | X | | | X |
| France | Nathalie HAYAUD | | | X | X |
| Germany | Anja HACKMANN | X | | | |
| | Claus HAAS | X | | | X |
| | Juliana REY | X | X | | |

| Country | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| Germany | Nicolaj HEUER | | | X | |
| | Heinz BÜLTER | X | | | X |
| Greece | Dimitris CHATZIANTONIOU | | | X | |
| | Eleni FOUFA | X | | X | X |
| | Vasileios VAGIAS | | X | | |
| Hungary | Balázs NÉMET | X | X | | |
| | Henrietta SZABÓ | X | X | | |
| | Nikoletta MAROSVÖLGYI | X | | X | X |
| Iceland | Björn GUNNLAUGSSON | X | | | |
| | Hafdís Inga INGVARSDÓTTIR | | X | | |
| | Fifa KONRADSDOTTIR | | | | X |
| Ireland | Margarete HOULIHAN | | | X | |
| | Majella COSGRAVE | X | | X | X |
| Italy | Sonia D'ILIO | X | | X | |
| | Renato CABELLA | | X | | |
| | Francesca CARFÌ | X | | | X |
| | Maria ALESSANDRELLI | X | | X | |
| | Sabrina MORO IACOPINI | X | | | X |
| Latvia | Elīna LAZDEKALNE | X | | X | X |
| | Kristine KRAFTE | X | X | | |
| | Sandra MATISA | X | X | X | X |
| Lithuania | Jurgita BALČIŪNIENĖ | X | | X | X |
| | Agnė JANONYTE | X | | X | X |
| | Beata VOLUJEVIČ | | | X | X |
| Luxembourg | Laurène CHOCHOIS | X | | X | X |
| | Oona FREUDENTHAL | X | | | X |
| Netherlands | Evan BEIJ | X | X | | |
| | Femke AFFOURTIT | | | X | X |
| | Gerda van den BOSCH | X | X | | |
| | Peter van IERSEL | X | | | X |
| Norway | Cecile BLOM | X | | | X |
| | Marie DAHLBERG PERSSON | | | X | |

| Country | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| Poland | Agnieszka BARANOWSKA-MOREK | X | | | |
| | Łukasz BELKIEWICZ | | X | | |
| | Krzysztof DOMAŃSKI | X | X | X | X |
| | Monika WASIAK-GROMEK | X | X | X | |
| Portugal | Isabel LAGINHA | X | | X | X |
| Romania | Simona DRAGOIU | | X | | |
| Slovakia | Dasa PAULIKOVA | X | | X | X |
| | Jana CHMELIKOVA | X | X | X | |
| | Lucia MURANIOVA | X | | | |
| | Michal PORUBIAK | | | X | |
| | Maria SKULTETYOVA | X | X | | |
| Slovenia | Marta PAVLIČ ČUK | X | X | | |
| Spain | Elena Maria SANCHEZ DIAZ | X | | X | X |
| | Laura ZAMORA NAVAS | X | | X | X |
| Sweden | Anneli RUDSTRÖM | X | X | | |
| | Jonas FALCK | X | | X | X |
| | Helena KRAMER | X | | | X |
| | Susanna NORRTHON RISBERG | X | | X | |
| | Jenny VIRDARSON | X | | | X |

## European Commission

| DG | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| DG GROW | Anna SCHUSTER | | | X | |
| | Riccardo ZORGNO | | | | X |
| DG SANTE | Ligia NEGULICI | | X | | |

### Candidate countries observers

| Country | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| Montenegro | Ilija GOJOVIC | | | X | |
| | Tatjana MUJICIC | | X | X | |
| Serbia | Snežana JOKSIMOVIĆ | X | | X | X |
| | Jelena GRUJIĆ | X | X | X | |

### Third country observers

| Country | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| Switzerland | Markus HOFMANN | X | | X | |
| | Olivier BLASER | X | X | | |

### Industry observers

| Organisation | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| A.I.S.E. | Cindy CHHUON | X | | X | |
| | Jan ROBINSON | X | X | X | X |
| Cefic | Amaya JÁNOSI | X | | | |
| | Camelia MIHAI | | X | | |
| | Irantzu GARMENDIA | | X | | |
| | Liisi DE BACKER | | | X | |
| EDANA | Luminița BARBU | X | X | | X |

### ECHA staff

| ECHA/unit[93] | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| A1 | Johanna SALOMAA VALKAMO | X | | | |

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

| ECHA/unit[93] | Name, surname | HelpNet Steering Group meeting | BPR Workshop | CLP Workshop | REACH Workshop |
|---|---|---|---|---|---|
| A2 | Anisa KASARUHO | | X | X | X |
| | Amandine JOMIER | X | X | X | X |
| | Anita TUOMAINEN | X | | X | |
| | Anthi MAKIOU | X | X | X | |
| | Carmen KLAUSBRUCKNER | X | X | X | X |
| | Eduardo BARRETO TEJERA | X | X | X | X |
| | Elena BIGI | X | X | X | X |
| | Erwin ANNYS | X | X | X | X |
| | Laure PAIN | | | | X |
| | Maciej BARANSKI | X | | | |
| | Malgorzata SZKLAREK | X | X | X | X |
| | Nicola TECCE | | X | | |
| | Peter SIMCIC | X | | | X |
| | Roxana BROASCA | X | X | X | X |
| | Ruben GONZALEZ VIDA | | | | |
| | Viorica NAGHY | X | X | X | X |
| A3 | Daniele APE | | | X | |
| A4 | Alexis QUINATANA SAINZ | | | | X |
| | Catherine CORNU | X | | | |
| | Eoin BRENNAN | X | | | X |
| | Elisa LIRAS | | X | | X |
| | Maria Jose BELMONTE SANCHEZ | X | | | X |
| B4 | Outi TUNNELA | | | X | |
| | Michaela SIMJAKOVA | X | X | | X |
| | Telmo Jorge VIEIRA PRAZERES | X | | | |
| C3 | Heidi EKHOLM | | | | X |
| C3 | Ignacio GONZALEZ RODRIGUEZ | | | | X |
| C4 | Katrin HALLING | | | | X |
| D1 | Carmen ESTEVAN MARTINEZ | | X | | |
| | Claudio PUTZU | | X | | |
| D1 | Bernhard KREBS | | X | | |
| | Eva VAKOVICOVA | | | | |
| D3 | Augusto DI BASTIANO | | | X | |
| D4 | Christina LOUKOU | X | | | X |
| E2 | Tomas ZBIHLEJ | | X | | |
| R3 | Marko POPOVIC | X | X | X | X |

# Annex III - Action points

## 16th HelpNet Steering Group meeting

| No | Action | Agenda item | Responsible | Status |
|---|---|---|---|---|
| 1. | Use HelpEx for discussing questions received from customers contacting several NHDs and shopping for an answer. | 2.3 | All | Open |
| 2. | Follow-up the pilot project on Q&A process. | 2.3 | ECHA | Ongoing |
| 3. | Follow ECHA's podcasts at echa.europa.eu/podcasts. | 3.1 | All | Closed |
| 4. | Provide the links to materials (website, animation, leaflet, infographic, social media posts) related to communication campaigns (poison centres, tattoo inks, etc.) to be launched by ECHA. | 3.1 | ECHA | Closed |
| 5. | Act as multipliers of the campaigns developed by ECHA and the Member State Communicators' Network on tattoo inks, UFI, SCIP, etc. | 3.1 | All | Ongoing |
| 6. | Send to REACH members the invitation to ECHA Forum Training on REF-10 Project – Integrated chemical compliance of products. | 3.2 | ECHA | Closed |

## REACH Workshop

| No | Action | Agenda item | Responsible | Status |
|---|---|---|---|---|
| 1. | Communicate to national helpdesks the deadline for the NONS once the communication campaign is ready. | 1.3 | HelpNet Secretariat | Closed |

## CLP Workshop

| No | Action | Agenda item | Responsible | Status |
|---|---|---|---|---|
| 1. | Follow-up with the Commission the first results of the impact assessment of the CLP revision (Q1-Q2 2022) and share with the HelpNet. | 1.1 | ECHA/COM | Ongoing |
| 2. | Ask the German helpdesk if they wish to follow-up the issue of toll manufacturer. | 2.1 | ECHA | Closed |
| 3. | Share information on the issue of improper packaging and related possible danger in your country (help-net@echa.europa.eu). | 2.2 | NHDs | Ongoing |

| | | | | |
|---|---|---|---|---|
| 4. | Follow-up on the FAQ 1856 on Article 29 of CLP and clarify whether further discussion is needed. | 3.1 | All | Closed |
| 5. | Share the Danish video 'How PCN can be submitted' to be used by other NHDs: https://mst.dk/kemi/kemikalier/reach-og-clp/faa-overblik-over-clp/oplysninger-til-brug-ved-forgiftning/ | 3.2 | ECHA | Closed |
| 6. | Go back to Germany on the subtitles of the PCN material and translation of the step-by-step guide. | 3.2 | ECHA | Closed |
| 7. | Share the link to the online sales campaign launched by Cyprus: http://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/DFCDB5380DAD2B6FC225863F004A94DB?OpenDocument | 3.2 | ECHA | Closed |
| 8. | Provide the Commission with a compilation of questions posted by national helpdesks in HelpEx concerning nicotine pouches. | 3.2 | ECHA | Closed |

## BPR Workshop

| No | Action | Agenda item | Responsible | Status |
|---|---|---|---|---|
| 1. | Share the link to the 'Practical guide for inspectors' (BEF-1 project), currently uploaded in S-CIRCABC: https://webgate.ec.europa.eu/s-circabc/w/browse/a294736f-4954-456a-8372-b26f9ee06061 (in case HelpNet members do not have access to the file, we suggest they liaise with their BPRS colleagues). | 1.2 | ECHA | Closed |
| 2. | Forward the invitation to the BPRS training event to be held remotely on 26 November to the BPR NHDs. Training material will be included. | 1.2 | ECHA | Closed |
| 3. | Share the link to the ECHA's open invitations for notifications: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/successful-declarations-of-interest In the column 'Topic', you will see whether the AS was subject to redefinition. Link to passed deadlines: https://echa.europa.eu/regulations/biocidal-products-regulation/passed-deadlines Link to upcoming deadlines: https://echa.europa.eu/regulations/biocidal-products-regulation/upcoming-deadlines | 3.1 | ECHA | Closed |

# Annex IV – Poll questions and results

## 16th HelpNet Steering Group meeting

### Agenda item 2.2 Report on unsolved/timed out questions

Poll 1 – Is this report useful for you?

| | |
|---|---|
| Yes | **31/75** |
| No | **2/75** |
| Cannot say | **18/75** |
| No answer | **24/75** |
| If you have any other suggestions, send them to help-net@echa.europa.eu | |

Poll 2 - Do you agree that the HelpNet Secretariat closes the questions up to 2020?

| | |
|---|---|
| Yes | **41/76** |
| No | **7/76** |
| If yes, which topics? | **25/76** |
| If you have any other suggestions, send them to help-net@echa.europa.eu | |

### Agenda item 2.3 HelpNet update on the new ways of working (NWOW)

Poll 3 - Based on the feedback outlined in the presentation, would you like to discuss today about:

| | |
|---|---|
| Redistribution criteria and equality | **8/77** |
| How to be informed of the redistribution | **17/77** |
| Deadline for responding | **12/77** |
| Other? | **2/77** |
| No answer | **53/77** |

### Agenda item 2.4 Role of HelpNet

Poll 4 - How do you think we could increase cooperation and harmonisation between national helpdesks and ECHA?

| | |
|---|---|
| Ad-hoc working groups | **18/81** |
| Regular videoconference per topic | **19/81** |
| Further cooperation on Q&As | **27/81** |
| Other | **0/81** |
| No answer | **39/81** |

## CLP Workshop

### Agenda item 1.2 Feedback from the CLP training and videoconferences

Poll 5 - What are the reasons that prevented you from using this opportunity to discuss during videoconference?

| | |
|---|---|
| No need | **8/60** |
| Lack of time | **14/60** |
| Lack of resources | **8/60** |
| Other | **4/60** |
| No answer | **33/60** |

## BPR Workshop

### Agenda item 1.2 Enforcement activities of the Forum BPR Subgroup

Poll 6 (closed session)

### Agenda item 3.2 Sharing experiences– open discussion

Poll 7: When dealing with COVID-questions, what was the most challenging?

| | |
|---|---|
| the amount of questions arriving in a very short time | **12/36** |
| cooperation difficulties due to teleworking | **0/36** |
| lack of resources (human and financial) | **2/36** |
| lack of support material | **0/36** |
| all of the above | **0/36** |
| No answer | **20/36** |

Poll 8: What was the strategy of your helpdesk in dealing with COVID-related questions?

| | |
|---|---|
| we did not have any specific strategy, it was 'business as usual' | **9/36** |
| we got additional resources (staff, financial) | **0/36** |
| we published support material on our website | **7/36** |
| other (specify) | **2/36** |
| No answer | **20/36** |

Poll 9: How did you facilitate the placing on the market of disinfectants?

| | |
|---|---|
| we decided temporarily not to enforce Article 95 | **8/36** |
| we implemented Article 55 (1) | **9/36** |
| we implemented COVID-specific national rules for disinfectants | **2/36** |
| all of the above | **1/36** |
| other (please specify) | **2/36** |
| No answer | **20/36** |

Poll 10: What topics do you find most challenging to reply?

| | |
|---|---|
| National authorisation of biocidal products or families | **2/36** |
| Classification, labelling and packaging of biocidal products | **5/36** |
| National procedures/laws governing transitional period | **3/36** |
| Treated articles | **3/36** |
| National fees | **0/36** |
| Enforcement | **3/36** |
| COVID-19 | **2/36** |
| Scope questions | **8/36** |
| No answer | **20/36** |