

Minutes of the 15th HelpNet Steering Group meeting and regulatory workshops

Time: 19-22 October 2020 WebEx session

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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.



15th HelpNet Steering Group meeting

1. Opening the 15th HelpNet Steering Group meeting

The HelpNet 15 events, organised for the members and observers of HelpNet, took place from 19 to 22 October 2020 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 15 events are listed in Annex III to these minutes.

1.1 Opening by the Chair

The Chair, Erwin ANNYS (ECHA) opened the 15th Steering Group meeting and welcomed representatives of the national helpdesks, observers from candidate and third countries, and observers from industry.

Erwin ANNYS started working at ECHA in June 2019 as the Head of the Support and Enforcement Unit, after a long career in chemical manufacturing companies, and chemical industry associations. He started at the Belgium association and worked at Cefic on REACH, GHS and CLP for 16 years.

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.

1.2 HelpNet 14 – follow-up action points

The Chair presented the list of action points from the previous Steering Group meeting in April 2019. With one exception concerning Forum HelpEx Q&As of interest to HelpNet, which will be addressed by the Forum Secretariat in the forthcoming Forum meetings scheduled from 26 to 30 October 2020, all action points were closed.

1.3 Approval of the HelpNet 15 draft agenda

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

2. Updates from the HelpNet Secretariat

2.1 Approval of the Handbook

Elena BIGI (ECHA) introduced the revised version of the 'HelpNet Handbook', finalised after one round of written consultation.

The feedback received from HelpNet members and responses from the HelpNet Secretariat were summarised in a room document available in S-CIRCABC. The most important changes – e.g. nomination of the Chair and alternate, virtual meetings and the time interval for publishing meeting documents before events – were discussed in the meeting.

Regarding discussions on virtual meetings as a matter of an emergency provision due to the experiences made during the ongoing COVID-19 pandemic, it was stated that virtual meetings have taken place even when there was not such a provision in the former HelpNet Handbook. Therefore, such a provision would effectively not be necessary. A question was then raised on whether the Handbook is written for a situation of a pandemic or whether it is written for a 'normal' situation. ECHA explained that the issue of virtual meetings does not only cover the pandemic situations, but also applies to the 'new normal' situation. Therefore, it would be necessary to include the possibility of organising virtual HelpNet meetings in a revised HelpNet Handbook, especially to avoid travelling and with respect to lowering CO₂ emissions and save resources.

A new clean version of the revised 'HelpNet Handbook' containing improvements agreed by the members will be circulated for approval by written procedure after the meeting.



2.2 Management of the ECHA Q&As

Peter SIMCIC (ECHA) outlined the new process of managing the Questions & Answers (Q&As) on the ECHA website, with the helpdesks (iTEX¹, REST², ICT³ and national helpdesks (NHDs)) as process owners. The process starts with proposal for a new Q&A from the ECHA Helpdesk (based on business intelligence from the questions received), from ECHA experts (specialists from the operational services) or the NHDs. A Q&A draft is then prepared in consultation with the relevant ECHA services, the legal affairs unit and NHDs (following the FAQ process outlined in the Handbook in this case). The process ends with the publication of the Q&As on the ECHA website including a notification to all parties involved in the updating process.

The Q&As are an essential instrument to ensure communication and awareness raising activities for companies on new and relevant topics and to keep national helpdesks and ECHA advice consistent and harmonised. There are about 1 600 Q&As published on the website and ECHA is working on their complete revision and update, including about 300 Q&A pairs⁴ agreed with the NHDs and published under the statement 'This answer has been agreed with national helpdesks', known as Frequently Asked Questions (FAQs).

The current Q&A revision started in April 2019 and will address the following points: remove outdated Q&As, remove duplications, merge fragmented Q&As into a comprehensive answer, simplify the language, use a harmonised approach to drafting, use a consistent editorial style, reorganise the current Q&A backbone by introducing new topics, scopes and chapters, and redevelop the page as a whole.

After the meeting, feedback on the Q&A management can be sent to the HelpNet Secretariat⁵ or to the Q&A functional mailbox⁶. The Secretariat will share ECHA's internal document on the management of ECHA's Q&As with the NHDs and regularly update them when new Q&As are published on ECHA's website. FAQ updates and relative communication will follow the process outlined in Section 3 of the Handbook. This outcome is very appreciated because NHDs base their advice explicitly on the ECHA FAQs, e.g. translating them into national language.

2.3 Visiting Programme

Viorica NAGHY (ECHA) informed the participants on the 70 visits which took place since 2008 when the visiting programme was launched by the Executive Director of ECHA. Viorica NAGHY illustrated the objectives and the benefits of a helpdesk visit and the proposed draft agenda and questionnaire aiming to collect information about the targeted helpdesk and its needs.

From May 2019 to January 2020, representatives of the Regulatory Support Team (REST) visited Luxembourg, Hungary, Denmark and Serbia; representatives of Montenegro, Serbia and Finland visited ECHA in May 2019. In addition, the Chair participated in the REACH helpdesk annual seminar in Luxembourg, and a representative of REST participated in the REACH & CLP Stakeholders' Day organised by the Serbian Ministry for Environmental Protection and the Chamber of Commerce.

Unfortunately, due to travel restrictions linked to the COVID-19 situation, the other visits planned for 2020 were put on hold. The HelpNet Secretariat wished to find out if national helpdesks are interested to continue the visiting programme and substitute onsite visits with virtual meetings.

It was concluded that, upon request, virtual visits could be replaced by training sessions (e.g. HelpEx), topical workshops, or bilateral/trilateral virtual meetings.

¹ IT External support - provides support to questions from industry, authorities and other stakeholders on ECHA's submission IT tools (REACH-IT, R4BP), technical assistance on IUCLID and Chesar and expert support on chemical information disseminated on ECHA's website.

² Regulatory Support Team – provides advice on REACH, CLP, BPR, SCIP and PCN obligations to industry, especially SMEs and maintaining the consistency of ECHA's support material. The team also supports national helpdesks in their work via the HelpNet network

³ ICT helpdesk - provides end user IT support to internal and external users

⁴ <u>https://echa.europa.eu/support/qas-support/qas-agreed-with-national-helpdesks</u>

⁵ <u>help-net@echa.europa.eu</u>

⁶ <u>qa-update@echa.europa.eu</u>



2.4 Update on the implications of the United Kingdom's withdrawal from the EU

Jukka MALM, the Deputy Executive Director of ECHA, informed that as of 1 February 2020, the United Kingdom (UK) became a so-called 'third country'. During the transition period which ends on 31 December 2020, the UK no longer participates in decision making and decision shaping in the EU institutions, agencies, bodies and offices, including the HelpNet; exceptions are exclusive and subject to strict interpretations (e.g. participation in the Biocides Coordination Group).

Jukka MALM informed on the Protocol on Ireland and Northern Ireland included in the Withdrawal Agreement and the objective of the protocol to avoid a hard border between Ireland and Northern Ireland. The protocol will enter into force at the end of the transition period, and thereby the UK has the obligation to implement a defined acquis communautaire in respect of Northern Ireland, including REACH, CLP, BPR, PIC and POP regulations, but not the Waste Framework Directive (WFD) or Drinking Water Directive (DWD), which are not listed in the Annex of the Protocol. More information will be provided once the outcome of the ongoing political negotiation between UK and Europe is defined.

Jukka MALM provided information about the transfer of substances registered in the UK since the beginning of the year, and particularly on substances registered by UK companies⁷ only. The amount of substances to be transferred to EU-based companies still remains high, which might confirm the industry's concern that these substances will disappear from the EU market.

To support companies, ECHA intensified its communication activities towards the end of 2020, and is reviewing the questions and answers (Q&As) for companies⁸ - e.g. Ireland/Northern Ireland Protocol, end of the transition period, Poison Centre Notifications (PCNs), and BPR mutual recognition.

During the Christmas break, between 24 December 2020 and 3 January 2021, the IT systems for industry remain open with regular monitoring; the regulatory advice support will be discontinued, but contact forms remain open. It was stressed that the parallel deadlines of Brexit, SCIP and PCN, together with the annual peak in PIC notifications, may lead to extended response times.

One national helpdesk asked how many, out of the 9 000 active REACH registrations⁹ in the UK, are related to companies based in Northern Ireland. It was clarified that the number of REACH registrations is low, with nine active registrations by seven registrants based in Northern Ireland¹⁰. The biocides and CLP activities are of the same magnitude, e.g. notifications to the Classification & Labelling Inventory, and no PIC export notifications from Northern Ireland.

In relation to access to IT systems and information concerning enforcement for example, it was clarified that, as a default, UK authorities are excluded from accessing EU information systems and databases. However, ECHA and the Commission agreed on exemptions which are necessary, for example, providing data through alternative ways to Northern Ireland authorities¹¹, so that they can enforce the relevant EU legislation in their territory.

NHDs welcome the updates of the web pages and new questions and answers providing advice to companies on the UK's withdrawal from the EU.

⁹ Information about REACH registrations in the UK:

https://echa.europa.eu/registration-statistics-infograph ¹⁰ Post meeting note:

⁷ https://echa.europa.eu/documents/10162/13552/uk_only_reg_en.xlsx/8065c461-f576-be5c-d450eb480737de7d

⁸ After the meeting, 110 Q&As were published on ECHA's website at:

https://echa.europa.eu/advice-to-companies-g-as/general

Northern Ireland registrations will not automatically remain active. A separate legal entity will be required for the Northern Ireland operation. This legal entity will need to be based in the United Kingdom (Northern Ireland).

Great Britain-based companies will have to carry out a legal entity change in REACH-IT, selecting the legal entity change type 'Split', before the end of the transition period. The registrations corresponding to the activity undertaken by the Northern Ireland legal entity will have to be transferred to the new company.

¹¹ The UK will have access only to cases that belong to Northern Ireland.



2.5 Choosing our future

Jukka MALM introduced ECHA's Programming Document, integrating the annual and multi-annual activity and resources planning. The comprehensive document – addressed to the European Commission and European Parliament – was discussed and approved by Management Board (MB) members in December 2020.

The MB will have to set priorities, in terms of activities, bearing in mind that the decisions taken now will have a long-term effect on ECHA's work and staff competences. The final budget 2020 and the budget proposal 2021 has to be submitted to the European Commission by 31 January 2021.

Jukka MALM referred to future uncertainties around the REACH and BPR fee income, and stressed that, as a result of the COVID-19 related savings, ECHA may be able to end 2020 without a budgetary deficit for REACH and CLP, though likely not avoiding it for biocides.

In the coming weeks, ECHA management will discuss which areas will be affected, to what extent and under which timeframe. Potential reductions, or negative priorities, do not necessarily mean that the tasks currently carried out in these areas are of low EU-added value. However, this will have an impact on the HelpNet as well, e.g. non-EU enquiries, currently replied by ECHA helpdesk might have to be transferred to national helpdesks. It was outlined that the transferal of those non-EU enquiries has to be thoroughly discussed in 2021, especially regarding the language capacities as well as the resources at NHD level. ECHA will continue to reply to IT technical questions and enquiries on its processes.

More information will come after the ECHA MB meeting in December.

3. ECHA activities

3.1 Guidance activities

The Chair presented the revised approach for developing ECHA guidance documents¹². The regulations for which ECHA is in charge require the Agency to provide guidance for industry and authorities while allowing freedom to define in which format such guidance needs to be provided.

Guidance documents addressed to authorities, justified in the early years of the regulatory processes, can now be gradually replaced by a more flexible approach to ensure a more dynamic and efficient buy-in during the consultation process.

Currently, the guidance documents are under the responsibility of process owners in the relevant operational units, and ECHA is moving to a tailored process for guidance development, where steps depend on the topic's needs, and incorporating implementation experience gained in the past years.

3.2 Forum activities

Maciej BARANSKI (ECHA) provided an update on Forum 2019-2020 activities, projects and training sessions, REACH and CLP priorities, IT support for inspectors and Forum, and the response of national enforcement authorities (NEAs) to the COVID-19 pandemic:

- Pilot project on cooperation with customs (2018-2020)
- REF-8 project: online sales of chemicals
- REF-10 integrated project on products
- Actions on REACH priorities 2019-2020:
 - Restrictions advice on enforceability of new restriction proposals; revising compendium of analytical methods for Annex XVII; restrictions addressed in other projects: REF-8, REF-10 and pilot project on cooperation with customs.
 - Authorisation REF-9 project on authorisation (2020-2022) and the Train for Trainers on 'Authorisation and REACH-OSH interactions' with participation of the BPR, CLP and REACH HelpNet members.

¹² Post meeting note: Albeit Guidance are soft law, they might have legal effects and practical implications, both for industry and ECHA that should not depart from them. As per the definition found in EU law textbooks and in this <u>recent paper of the European Parliament</u>, guidance are technically instruments of soft law 'which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal effects, and that are aimed at and may produce practical effects.



- 6 (36)
- REACH Registration REF-7 project on registration; pilot project on recovered substances; enforcement of ECHA decisions – reviewing and streamlining the 'interlinks guide' describing processes for agile cooperation between ECHA and NEAs on enforcement of specific cases and ECHA decisions (e.g. dossier/substance evaluation or registration revocation).
- Action on CLP priorities 2019-2020CLP pilot project on classification of mixtures (2020-2023)
- Action on BPR priorities 2019-2020
 - BEF-1: Treated articles (2018-2020)
 - BEF-2: Biocidal products (2021-2023)
 - BPR Training for trainers 2020

As a follow-up of two actions of the REACH Review 2017, Forum investigated and mapped the 'REACH-OSH enforcement interactions'¹³ and will conduct a two-year pilot of voluntary annual reporting of national enforcement activities¹⁴ to ECHA by submitting data from 2021 and 2022.

In response to the COVID-19 pandemic, NEA resources diverted to duties related to pandemic response e.g. special decisions for active substances for disinfectants and some onsite inspections have been postponed or transferred to desktop controls.

HelpNet correspondents are welcome to take part in the remote streaming of the Training for Trainers focusing on Authorisation and REACH-OSH interactions taking place on 25-26 November and the BPR Training for Trainers focusing on the biocides definition and borderlines taking place on 18 November.

3.3 Communication activities

Johanna SALOMAA-VALKAMO, Head of ECHA's Communications Unit, presented the latest and most important communication activities relevant for HelpNet, namely the rebranding of ECHA, the upcoming website revamp and communication collaboration with Member States.

- Branding or corporate identity project review the current perception of ECHA and become more approachable, more modern and less technical and bureaucratic in communication; focus on the brand story and values attached to ECHA as an organisation.
- Preparation for a customer insight research to set the future of the ECHA website. The objective of
 the survey is to give us a better understanding of how and why ECHA as a brand is perceived by
 our stakeholders, partners and interested members of the general public (consumers); reach out
 to a wider audience, including non-expert decision makers.
- Communicating successfully on chemicals safety and lessons learnt; using social media to manage reputation (i.e. microplastics) and topical issues, e.g. new requirements for safety data sheets, EUCLEF, SCIP, and Poison Centres.

Johanna SALOMAA-VALKAMO invited representatives of HelpNet to act as multipliers, and use the communications material prepared by ECHA to support duty holders in complying with their SCIP and Poison Centre obligations:

- SCIP¹⁵ database launched on 28 October, communication materials website, animation, leaflet, infographic, social media posts – and webinar¹⁶ on 19 November 2020.
- Poison Centres animations and illustrations for successful poison centre notifications, <u>LinkedIn</u> <u>group</u> discussions, dedicated website for news.
- EU nanomaterials observatory (EUON) study on public perception of nanomaterials and their risks published in November, customer insight project to improve the EUON website and content. Interested HelpNet members and observers willing to write a nanopinion¹⁷ were invited to contact ECHA.

¹³ Action 12 (2): 'The Commission will propose the following concrete steps to remove the overlaps and clarify the interface between REACH and OSH (...): improve the coordination of national enforcement authorities of REACH and OSH legislation'.

¹⁴ Action 13(2) 'ECHA's Forum and Member States are requested to establish comparable parameters on enforcement. On the basis of those parameters, Member States should report annually to ECHA for the purpose of monitoring enforcement activities by Member States'.

¹⁵ <u>https://echa.europa.eu/scip</u>

¹⁶ <u>https://echa.europa.eu/webinars/all-webinars</u>

¹⁷ <u>https://euon.echa.europa.eu/nanopinion</u>



Enforcement communication packages on three¹⁸ Forum projects including press releases, video animations, podcasts, etc.

Representatives of national helpdesks emphasised the importance of the Communicators' Network, noting however, that not all members of the network are necessarily experts in communication, but responsible for the implementation of the EU chemicals regulations. The national helpdesk of Luxembourg remarked that the AskREACH project can be promoted together with the SCIP duties, by national authorities responsible for the Waste Framework Directive.

3.4 EU Chemicals Legislation Finder (EUCLEF)

Elisa LIRAS and **Adam ELWAN** (ECHA) presented the **E**uropean **U**nion **C**hemicals **LE**gislation **F**inder¹⁹ (EUCLEF), the search engine for regulatory information on chemicals enabling companies, especially SMEs, to find out how their substances are being regulated in the EU and what legal obligations they have.

EUCLEF is funded by the European Commission²⁰ and gives companies access to a free-of-charge overview of 40 pieces of EU chemicals legislation they may need to comply with. Through EUCLEF, companies will have access to a wide range of legislative information on areas managed by ECHA and outside the scope of ECHA's remit, such as cosmetic products, pesticides, waste, toy safety, food safety, etc.

Interested parties can search for a substance to find out how it is regulated under different pieces of EU chemicals legislation or by individual pieces of legislation to find out about their scope, exemptions, regulatory activities and lists of impacted substances, together with links to full legal texts in all EU languages.

EUCLEF will also support the work of the European Commission and national authorities, as it will help them identify substances for which there may be regulatory overlaps or gaps. Information on other pieces of chemicals legislation will be integrated in the tool in the coming years.

Elisa LIRAS invited national helpdesks and observers to share ECHA's posts, use the EUCLEF banners, publish their own news releases based on ECHA's, promote the regulatory advice service, and help ECHA reach out to authorities outside of HelpNet who deal with supporting EUCLEF legislation:

- Webinar getting to know EUCLEF²¹
- Video tutorial navigating EUCLEF²²
- Leaflet: what is EUCLEF²³?

Regulatory advice and technical support can be requested through the contact forms²⁴ of ECHA.

3.5 First ideas on the Chemicals Strategy Sustainability

The Chair introduced the objective of the EU's chemicals strategy²⁵ - aiming to better protect citizens and the environment and boost innovation for safe and sustainable chemicals.

The European Commission published the 'Chemicals strategy for sustainability towards a toxic-free environment'²⁶ on 14 October 2020. It is part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal.

The Chair introduced the key actions:

- banning the most harmful chemicals in consumer products and allowing their use only where essential;
- taking into account the cocktail effect of chemicals when assessing risks from chemicals;

¹⁸ Pilot Customs II project, BEF-1 project on treated articles and REF-7 project on obligations of importers and manufactors to register their substances.

¹⁹ <u>https://echa.europa.eu/legislation-finder</u>

²⁰ Europe's programme for small and medium-sized enterprises.

²¹ https://echa.europa.eu/-/getting-to-know-the-eu-chemicals-legislation-finder-euclef-

²² <u>https://www.youtube.com/watch?v=0A--zrwwdio&feature=youtu.be</u>

²³ <u>https://echa.europa.eu/documents/10162/29112261/euclef_leaflet_en.pdf/b904628a-09c8-b4f0-6116-36eb1cb22e66</u>

²⁴ <u>http://comments.echa.europa.eu/comments_cms/Contact_EUCLEF.aspx</u>

²⁵ <u>https://ec.europa.eu/environment/strategy/chemicals-strategy_en</u>

²⁶ https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf



- phasing out the use of per- and polyfluoroalkyl substances (PFAS) in the EU, unless their use is essential;
- boosting the investment and innovative capacity for production and use of chemicals that are safe and sustainable by design, and throughout their life cycle;
- promoting the EU's resilience of supply and sustainability of critical chemicals;
- establishing a simpler `one substance, one assessment' process for the risk and hazard assessment of chemicals;
- playing a leading role globally by championing and promoting high standards and not exporting chemicals banned in the EU.

National helpdesks welcomed the ambitious strategy, stressing the importance of tailor-made financing and support to substitution and innovative products.

Closing of the Steering Group meeting

The Chair summarised the main action points and thanked all participants for their contributions to the meeting.



BPR Workshop

Erwin ANNYS (ECHA), the Chair of HelpNet, opened the workshop by welcoming the representative of the European Commission (DG SANTE), national helpdesks, observers from candidate and third countries, and industry observers. The names of the participants attending the workshop are listed in Annex III to these minutes.

1. Update on BPR hot topics

1.1 Update from the European Commission

Ligia NEGULICI (European Commission, DG SANTE) presented an update on the hot topics related to the implementation of the BPR. Ligia NEGULICI covered the impact of the COVID-19 pandemic on biocides, the borderline between biocides and cosmetics, and the status of active substance (AS) evaluations in the Review Programme (RP). In addition, the presenter talked about renewals, the early review of ASs and Article 55(3) derogations for the protection of cultural heritage.

The following points were highlighted:

- The derogation under Article 55(1) covers products containing approved substances and active substance/product types (AS/PTs) not covered in the RP. National rules apply to both authorisation of AS/PT in the RP and to possible derogations due to the COVID-19 pandemic.
- The Commission published disinfectant related lists and guidance on the applicable legislation for hand-cleaners and hand-disinfectants, clarifying the borderline between the BPR and the Cosmetic Products Regulation (e.g. claims and other labelling elements).
- The Commission received more than 450 notifications related to emergency permits under Article 55(1). Such permits were primarily granted for PTs 1 and 2, but also PT 4. Some permits concerned one PT 6 product (a preservative for aircraft fuels).
- Seven Member States requested a derogation under Article 55(3) for the use of '*in situ* generated nitrogen' for the protection of cultural heritage. Museums are taking steps towards submitting an application for Annex I inclusion for '*in situ* generated nitrogen'.
- Under Article 15(1), an early review was initiated for iodine, polyvinyl-pyrrolidone (PVP)-iodine and zineb due to concerns over their endocrine-disrupting properties. Upon a request from Denmark, tolyfluanid will also be subject to early review due to the cat 1B carcinogen classification of one specific metabolite.
- Since 1998, only 42 % of the evaluations of AS/PTs in the RP have been finalised. Delays impact the level of protection of human health and the environment, prevent the creation of a level-playing field for companies and have effects on Member States and ECHA resources. To unlock the situation, ECHA launched the active substance action plan.
- The presenter covered other topics such as: the way forward for the renewal of anticoagulant rodenticides, the update of the BPR annexes II and III concerning information requirements, reporting under Article 65(4) and presented a BPR scope issue (the 'Darie' case).

1.2 The UK withdrawal from the EU

Camilla BUCHANAN (ECHA) presented the practical consequences related to the UK withdrawal from the EU. The presenter outlined the changes that are applicable during the transition period as well as those that apply after the transition period is over. Camilla BUCHANAN also provided an update on the Protocol on Ireland and Northern Ireland (NI).

The following points were highlighted:

• During the transition period, the UK cannot act as leading authority at EU level (e.g. evaluating competent authority (eCA) for active substance (AS) approvals/union authorisations (UAs), or as a reference Member State (refMS) for Mutual Recognitions (MRs). Pending applications were transferred to other eCAs. For pending MRs, the applicants need to find a new refMS.



- Until the end of the transition period, UK national authorisations (NAs) are valid in the UK, UK companies can be 'authorisation holders' and can be on the Article 95 list (but they need to find an EU representative as soon as possible). Simplified authorisation notifications to other EU/EEA Member States are valid.
- After the transition period, the UK will apply its own laws, except in NI. Biocidal Product (BP) authorisations based on mutual recognition of a UK authorisation remain valid (until expiration).

NI companies will need their BPs to be authorised under the BPR by the UK authorities. MRs of NI authorisations in EU/EEA Member States will not be possible. BPs shipped from NI to the EU will not be considered as imports. NI BP authorisations will not be processed via R4BP 3, such applications will be directed to UK authorities.

1.3 Active substance action plan

Carmen ESTEVAN MARTINEZ (ECHA) reported on the progress made in speeding up the evaluation of active substances in the Review Programme (RP). The presenter outlined the ongoing actions for ECHA, competent authorities and the Commission and described how joint efforts, by all parties, can contribute to progressively unblocking evaluations, moving forward the approval of active substances.

The following points were highlighted:

- The active substance (AS) action plan was set to identify ways to accelerate the evaluation of substances in the RP with the objective to meet the 2024 deadline.
- A number of actions have been identified:
 - Prioritisation of dossiers an ECHA contact point is appointed for each evaluating competent authority (eCA) to jointly discuss priorities and plan assessments.
 - Support to eCAs ECHA will provide technical, scientific and regulatory support to eCAs and help facilitate the interaction with applicants.
 - Streamline the peer review by improving the effectiveness of the Biocidal Products Committee (BPC) Working Group.
 - Reduction of complexity by focusing assessments on safety and efficacy, simplifying the endocrine disruptors (ED) assessment and by facilitating Member State competent authorities (MSCAs) access to key information (e.g. guidance documents).
 - Harmonised assessment of confidentiality claims ECHA will develop guidelines to support MSCAs.
- It is expected that the action plan reduces the cases in peer review, increases the draft competent authority reports (CARs) entering peer review and the number of BPC opinions delivered. Overall, apart from reducing the backlog of dossiers in the pipeline, it promotes cooperation among the parties involved.
- One HelpNet member asked whether there were any expected requirements or criteria (e.g. similar to the ED criteria) that may pose an additional challenge to finalising the evaluation of substances by 2024. It was explained that the inclusion of the ED criteria, indeed, heavily impacted the progress of the evaluations and since the entry into force of the ED assessment in 2018, the number of the finalised assessments has decreased significantly. Furthermore, Brexit posed an additional challenge, but we do not expect another piece of guidance to have such a significant impact as the ED assessment.

2. Support and Enforcement

2.1 Update from the Forum BPR Subgroup

Nicola TECCE (ECHA) presented the activities of the Forum BPR Subgroup and the state-of-play with its Working Groups, namely the BEF-1 on treated articles and the REF-8 on online sales. The presenter also gave an overview of the upcoming training for national inspectors and the on-going practical issues for the enforcement of the BPR.



The BEF-1 project on treated articles reached its final phase and the report already went under written consultation among the BPRS members and national coordinators of the BEF-1. Its adoption and publication²⁷ on the ECHA website²⁸ are expected by the end of 2020.

The project focused mainly on the labelling requirements for treated articles (TAs) in accordance with the BPR and presence of legal/illegal active substances included in such TAs. Within the project more than 1 100 companies were inspected and almost 2 000 treated articles (including both articles and mixtures) were checked.

The results of the project were presented:

- Most of the checked articles and mixtures (considered TAs) were manufactured within the EU.
- More than 80 % of controlled articles and almost all the controlled mixtures were labelled.
- The level of incompliance of the labels of the checked TAs was high, especially for articles: almost 50 % of articles were labelled incorrectly (the most common incompliance was the lack of the active substance name), whereas labelling of 23 % mixtures was improper.
- The amount of active substances not allowed within the EU and used in the checked TAs was very low (i.e. 2.5 %).

The actions taken by inspectors as a result of stated incompliances included:

- Written and verbal advice.
- Fines and administrative orders.
- Public prosecutor, and criminal complaints.
- Follow-up inspections.

The ongoing work on REF-8 on online sales is currently in its operational phase. As the module focuses solely on the information available on the internet, there will be no requirement to purchase the biocidal products to complete the inspections. The project covers biocidal products authorised both under Article 17 of the BPR as well as made available under transitional measures (Article 89 of the BPR). The project is expected to reach its reporting phase in 2021.

Nicola TECCE mentioned that an upcoming training for national inspectors is planned on 18 November 2020. The event will be held remotely. The training will cover borderline obligations between the BPR and other chemicals legislation. The presenter invited the participants to attend the event and analyse the training material as shared with the invitation to the training event.

Finally, an update on the on-going 'practical issues for the enforcement of the BPR' was delivered. Nicola TECCE briefly summarised the discussion that the BPRS members are currently having on three main issues: i) treated articles with permethrin; ii) biocides borderline issues; iii) biocidal products with unstable active substances.

2.2 Development of BPR support

Claudio PUTZU (ECHA) presented the development of the BPR support material.

On the topic of guidance updates, the speaker referred to the document 'Update on ECHA's guidance activities 2020-2021'presented at the 89th Competent Authority (CA) meeting and explained that the document covers the key priorities for guidance development in 2020-2021. The audience was informed on the endorsement of guidance related to Article 95 relevant data in the context of active substance renewals.

It was highlighted that ECHA prioritised the development of five guidance documents and the current state of work was described. Recently, the drafting started for developing guidance on the 'risk to pollinators from the use of biocides' and for updating the guidance on human health information requirements. Interim documents for both projects will be systematically published on the ECHA website. At the moment, only a section related to the pollinators guidance is available, but ECHA plans to

²⁸ Forum enforcement projects:

²⁷ Post meeting note: The 'Report of the first harmonised enforcement project on treated articles' (BEF-1) was published in December 2020:

https://echa.europa.eu/documents/10162/13555/bef 1 report en.pdf/8e0e4520-3c41-92d2-0e9f-199109ee8f5f

https://echa.europa.eu/it/about-us/who-we-are/enforcement-forum/forum-enforcement-projects



introduce also a section for human health. The presenter also gave a brief overview on the updates of submission manuals.

Claudio PUTZU then presented the new features of the BPR dissemination site, highlighting the changes related to the content of information on active substances. He elaborated on the feature that allows substances to be filtered on the basis of the regulatory process (e.g. new vs. Review Programme vs. Annex I substances) and informed that ECHA is currently working on including the missing Annex I entries into the dissemination site.

Finally, the presenter reminded the participants of the COVID-19 updates available on the ECHA website and gave an overview of the information provided in the page.

One HelpNet member asked about the publication of the list of national web pages on transitional measures under Article 89 of the BPR. It was clarified that the list has already been published on the ECHA web pages and the presenter agreed to share the link with all the participants.

Furthermore, the HelpNet member asked whether requests for updating national links appearing on the COVID-19 ECHA web page should be addressed through the biocides' functional mailbox, or ECHA contact forms. ECHA will reflect on this internally and inform attendees at a later stage²⁹.

2.3 European Chemical Industry Council (Cefic) support activities by the European Biocidal Product Forum (EBPF)

Camelia MIHAI (Cefic-EBPF) presented the support activities on biocides provided by the European Biocidal Product Forum (EBPF).

The presenter gave an overview of EBPF, the biocides Sector Group of Cefic. Camelia MIHAI described the structure of EBPF, its goal and the type of support it provides to members as well as the challenges they face.

EBPF reacted to the COVID-19 crisis by helping companies understand their obligations under the BPR and equivalent national laws, and facilitating the placing of disinfectants on the EU market. As a response to the pandemic, the Cross-Industry Alliance (comprising EBPF, A.I.S.E. and Fecc) was created, at the initiative of EBPF.

Among other actions, the alliance developed the practical guide³⁰ on fast-tracking the supply of disinfectants. At the same time, Cefic established a COVID-19 Helpdesk³¹, which provided rapid and tailored support to companies, particularly during the first months of the crisis.

2.4 International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) support activities

Elodie CAZELLE (A.I.S.E.) gave an overview of the BPR support activities provided by A.I.S.E., representing the European manufacturers of cleaning, hygiene and disinfectant products, an essential sector in the fight against COVID-19³² due to its portfolio of products and services.

The presenter described A.I.S.E. as a network of national associations, corporate members and chain partners across Europe. Through this extensive network, A.I.S.E. represents over 900 companies supplying household and professional cleaning products and services across Europe. Elodie CAZELLE explained that disinfectants, insecticides, repellents and preservatives are the relevant biocidal product types for A.I.S.E. members.

Elodie CAZELLE highlighted the general support activities that A.I.S.E. provided to its members in 2019-2020, particularly on the new biocidal product family (BPF) concept, efficacy matters in relation to disinfectants and the availability of in-can preservatives.

²⁹ It was clarified after the meeting that updates for the COVID-19 web page should be requested through the ECHA contact forms, choosing the option 'ECHA website': <u>https://comments.echa.europa.eu/comments_cms/Contact_Other.aspx</u>

³⁰ Practical Guide on Fast-Tracking the Supply of Disinfectants during the Covid-19 Pandemic under the EU Biocides Rules: <u>https://hnlkg4f5wdw34kx1a1e9ygem-wpengine.netdna-ssl.com/wp-</u>

content/uploads/2020/06/Practical-Guide-on-Covid-19-and-Fast-Tracking-Supply-of-Disinfectants-v2.pdf ³¹ https://cefic.org/the-european-chemical-industry-covid19-help-desk/

³² <u>https://www.aise.eu/our-activities/covid-19.aspx</u>



Furthermore, the presenter elaborated on activities related to Brexit and the COVID-19 crisis, including cooperation with the European Commission and other industry associations (e.g. the Cross-Industry Alliance).

Finally, Elodie CAZELLE presented the support material developed for members and consumers³³.

2.5 European association of chemical distributors (Fecc) support activities

Simina DREVE (Fecc) presented the support actions carried out by Fecc, the European Association of Chemical Distributors.

Fecc represents over 1 600 distribution companies many of which are small and medium-sized enterprises, covering all chemical sectors. The presenter outlined the variety of activities covered by distributors, their role and position in the chemical value chain.

Simina DREVE presented the topics and committees where Fecc is involved, highlighting its contribution in the Biocidal Products Committee (BPC) and in the activities of the Safety, Health and Environment Committee (SHE).

Furthermore, the presenter elaborated on the Fecc guidance on storage tank management for biocidal active substances and explained the importance of this document for both chemical distributors and inspectors.

Closing of the BPR Workshop

The Chair listed the action points as the outcome of the workshop, that would be circulated shortly after the meeting and closed the BPR Workshop.

³³ Q&As on the consumer portal:

https://cleanright.eu/en/fag.html#collapse-catitem-336



CLP Workshop

Opening by the Chair

Erwin ANNYS (ECHA), the Chair of the HelpNet, opened the workshop welcoming participants from national helpdesks, the representatives of the European Commission (DG GROW and DG ENV) and the observers. The list of participants is available in Annex III to the minutes.

The Chair referred to the challenging situation due to the COVID-19 pandemic and current working circumstances on the online platform and gave information about the WebEx functionalities.

The Chair informed the participants about an additional presentation on the Chemical Strategy for Sustainability given by a representative of the European Commission and proposed to add it to the previously circulated agenda. The agenda, including the proposed item, was approved.

The Chair presented the status of action points of the previous CLP Workshop on 25 May 2020.

1. Updates from the European Commission

1.1 Updates from the European Commission

Anna SCHUSTER (European Commission, DG GROW) provided an update on the pending action points. The action point 'inclusion of fuels in Annex II to CLP' needs further discussion. It has been postponed due to preparations related to the second amendment of Annex VIII to CLP and the Chemical Strategy for Sustainability. It is not forgotten, and the Commission will come back to it.

Regarding the action point 'nail and lash glue' (whether or not they are considered as cosmetics), the Working Group on Cosmetic Products met in June, but no agreement³⁴ was reached yet. The Cosmetics unit in DG GROW is in the lead and will bring the issue to the next meeting of the Cosmetic sub-group working on Borderline Products foreseen for the beginning of 2021. The results will be shared with the HelpNet.

Regarding the finalised action point on Article 29(1) and (2) read in combination with Annex I, Section 1.5. on Exemptions from labelling and packaging requirements, Anna SCHUSTER thanked for the input given by Sweden on Article 29 on labelling exemptions, in particular to paragraphs 1 and 2.

Furthermore, the representative of DG GROW explained that they had worked over the summer on the Workability Amendment to Annex VIII to CLP. In terms of legislative procedure, linguistic versions had been prepared and proofread by national experts ahead of the scrutiny period after adoption by the Commission. The Commission highly appreciated the comments submitted by the MSCAs. The amendment in practice covers two legislative acts: one to amend Article 25 on supplemental labelling, and another to amend Annex VIII to CLP. They were adopted on 31 August and the scrutiny period started. The Council had already notified they had no intention to object. The scrutiny period will end on 31 October and the expected publication date is at the beginning of November 2020. The entry into force will be the day after publication: this is very important to ensure entry into force before the first compliance date (1 January 2021)³⁵. Concerning the question on a possible postponement of the first compliance date, Anna SCHUSTER clarified that the Commission has no mandate to postpone, so it will not happen.

A national helpdesk raised their concern about the interpretation of Article 29(1) and how it would be reflected in the Guidance. ECHA explained that both the Guidance on Annex VIII and on labelling are under revision (to consider the changes in the legal text of Annex VIII) and the interpretation of Article 29(1) is covered.

³⁴ See useful link to this group:

https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products en ³⁵ Post-meeting note: By now the amendments are published and entered into force: COMMISSION DELEGATED REGULATION (EU) 2020/1676 of 31 August 2020 COMMISSION DELEGATED REGULATION (EU) 2020/1677 of 31 August 2020



1.2 Chemicals Strategy for Sustainability

Elena MONTANI (European Commission, DG ENV) introduced the EU Chemicals Strategy for Sustainability³⁶, starting by highlighting the importance of the EU chemical sector in the EU, and worldwide.

Elena MONTANI explained the background of this strategy, the first deliverable on the zero-pollution ambition of the Green Deal³⁷, and the policy evaluations which served as basis for the basis for the actions announced. The presenter provided an introduction to the 2030 vision on 'towards a toxic-free environment' and illustrated it with an inverted pyramid for chemicals (the toxic-free hierarchy). Elena MONTANI presented a plan for getting there with the following five building blocks (some examples here in parenthesis for each block, taken from the presentation):

- (1) boosting innovation (promote and support the transition to safe and sustainable by design, identify key chemical value chains, promote non-toxic material cycles);
- (2) strengthen legislation for better protection of human health and the environment (the most harmful chemicals are not contained in consumer products, concept of essential uses);
- (3) simplifying and consolidating the legal framework (one substance, one assessment; strengthen compliance; enforcement and market surveillance);
- (4) a comprehensive knowledge base (long-term EU research, chemical properties and uses, framework of indicators); and
- (5) setting the example globally with objectives and targets beyond 2020 (GHS, common standards, and innovative assessment tools, sound management of chemicals in international cooperation).

The strategy announced over 70 actions³⁸ for which implementation is starting now, with the maximum participation of stakeholders and all relevant actors.

The Chair invited Elena MONTANI to join the REACH workshop on the following day.

2. Updates from ECHA

2.1 Update from CARACAL

Ari KARJALAINEN (ECHA) informed participants about the outcome of the CARACAL meetings that took place in July and September 2020. The focus of his presentation was on the 17th ATP (borates and copper compounds); completed and on-going GHS activities; and some additional classification issues (aerosols, bioelution, endocrine disruptors).

One national helpdesk questioned the validity of the additivity calculation method for STOT. Ari KARJALAINEN clarified that the additivity for CMR and STOT is only a thought starter and working documents that can be shared will appear in the future.

The Chair ran a poll about the presentation.

2.2 Poison Centre Notification – support material

Pedro ROSELLÓ VILARROIG (ECHA) introduced the available support material for Annex VIII. The presenter detailed the options available for toll formulators, and how non-EU suppliers can help their EU-based importer comply with their duties while keeping their formulation confidential.

The presenter highlighted the fact that the IT release including the second amendment changes will be published on 26-28 October before the actual legal text (expected at the beginning of November). The presenter concluded that since the legal text is stable and the support material is quickly reflecting the changes, ECHA will rely on the national helpdesk to reply to more questions on this topic.

One national helpdesk asked if the 'Guide to dossier preparation and submission' will be updated to include the changes introduced by the second amendment, and if the editable version will be made

³⁶ <u>https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf</u>

³⁷ <u>https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en</u>

³⁸ https://ec.europa.eu/environment/pdf/chemicals/2020/10/Annex.pdf



available again to the HelpNet. ECHA explained that there is work ongoing to update the support material, and in relation to the ECHA Submission Portal, the 'PCN: a practical guide' is being prioritised.

The Chair asked the national helpdesks to share their experiences in replying to PCN questions. The transitional period was the most frequent topic, as perceived by the national helpdesks.

Other topics were addressed: handling of the UFI, and placement on the label; roles and duties under Annex VIII. Then there were a number of specific topics that were tackled on the spot. ECHA explained that due to the different ways Member States can connect to the ECHA systems, and the different paces of implementation of each Member State, companies will need to contact them individually to get conclusive replies. The representative of the Commission reminded that notifications have to be done based on the form in which the mixtures are placed on the market, including aerosols. They can be in liquid or gas phase, and that is the form that should be reported in the poison centre notification.

Regarding the companies contacting them, the number of toll formulators; producers of plant protection and biocidal products; but also companies outside the Member State where the receiving national helpdesk was placed, and even outside the EU was noticeable.

The Commission acknowledged that online sales is a difficult discussion as several practical aspects have to be considered when looking at it. The issue needs to be discussed at a more general level as it impacts many other pieces of legislation: not only Annex VIII to CLP. The Chair pointed out to the ongoing REACH-EN-FORCE-8 project³⁹ on internet sales, which may provide interesting lessons.

Another issue that stirred discussion was the definition of consumer, professional and industrial use, and in particular the difference between the two last ones. ECHA informed that there is a specific discussion going on at CARACAL⁴⁰.

3. Topics proposed by national helpdesks

3.1 Classification and labelling of TiO₂ and mixtures containing TiO₂

This presentation is related to the discussion on the HelpEx question 17412 in HelpEx.

Anja KNIETSCH (Germany) pointed out the content of the 14th ATP to the CLP Regulation (Commission Delegated Regulation (EU) 2020/217) concerning the harmonised classification and labelling of titanium dioxide (TiO₂.). The 14th ATP amends Annexes II, III and VI to the CLP Regulation. The presenter mentioned that the TiO₂ entry was a special one, as it refers to both the specific form of the substance (powder), and the particle presence (particles with aerodynamic diameter \leq 10 µm).

The German helpdesk had elaborated a six-page guide to help industry in understanding such a complex entry especially when it comes to labelling. They offered to discuss the content of the guide with the aim to publish a common HelpNet document. The presentation ended with two questions to the HelpNet: could they share the German interpretation and recommendation? Could the HelpNet provide a common view?

The Commission offered their help in the implementation of this new classification and labelling, starting by sharing their opinion that the requirement for the EUH 212 statement applies only to the labelling of those solid mixtures containing TiO₂ that are not classified. They also acknowledged the issues identified with several translations of the entry, which are currently in the process of being corrected, so that companies will be in the position to better comply with this harmonised classification and labelling, when it becomes applicable (1 October 2021)..

The Chair and Anja KNIETSCH agreed to discuss how to translate the guide, before sharing it with the HelpNet.

An industry observer asked if the entry covers impurities, as they deal with a number of UVCB substances and TiO₂ as such may be present in them. They also enquired about the definition of 'solid'.

³⁹ REACH-EN-FORCE-8: Enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold on-line:

https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

⁴⁰ Thought-starter paper CA/19/2020 presented in CARACAL-34. See also HelpEx 17823.



3.2 Overlapping legislation on electronic lighters

Caroline WALSH (Ireland) initiated the presentation referring to the discussion on HelpEx question 17306: Where an electronic lighter comes under the scope of both the CLP Regulation and the safety standards listed under the General Product Safety Directive, which one takes precedence?

Caroline WALSH presented the overlapping legislation of the case and analysed their differences (CLP label versus GPSD label). The presenter also had real life examples of labelling and safety data sheets for electronic lighters. Producers of electronic lighters may not be aware of which legislation applies. There would be a need to add legal awareness (CLP versus safety laws) – also through guidance documents (like ECHA guidance on substances in articles or CLP).

Some national helpdesks agreed that it was excessive to have several labelling requirements which are so similar. One of them acknowledged that they have not found any electronic lighter complying with CLP labelling.

The Chair proposed to launch a written procedure to understand the support of the HelpNet to look into the case, by replying to the questions posed by the Irish helpdesk. Depending on the outcome⁴¹, the HelpNet Secretariat would consider setting up a working group to engage in discussions with the European Commission.

3.3 Generation of new data under CLP

Elena ZIDAROVA (Bulgaria) presented the case where a company requested to halt the harmonised classification procedure to generate information relevant to it. This was a follow up for the discussion in the HelpEx platform (HelpEx question 16958).

In summary, the Bulgarian competent authority had received a request from industry to stop the procedure for a substance, to be able to provide new information, that would question the proposal. After presenting the case, she asked if other national helpdesks or competent authorities had faced the same or similar situations, and for their opinion about this case.

The representative of the Commission pointed out that in CLP Article 37(6) industry is encouraged to provide new information, though indeed there is no legal space to halt or stop the harmonisation procedure.

The Chair mentioned that he knew about a similar case, where a company wanted to provide data against a proposal for harmonised classification. In that case, the new information resulted in supporting the proposed harmonised classification, so not being able to stop the procedure did not make a difference.

Closing the CLP Workshop

The Chair closed the CLP Workshop, thanking all the participants for their active involvement and the lively discussions that had taken place. He pointed to two possible actions points as the outcome of the workshop, that would be circulated shortly after the meeting.

⁴¹ Post meeting note: The outcome of the written procedure is available in S-CIRCABC (path: CircaBC/echa/HelpNet/Library/02 Steering Group/HelpNet 15).

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. Update from the European Commission

1.1 Update on the implementation of REACH

Riccardo ZORGNO (DG GROW, European Commission) provided an update on the recent legislative modifications and other acts issued by the Commission under REACH, including the update of REACH annexes, other implementing acts and developments on the REACH authorisation process.

The Draft Commission Regulation amending REACH as regards Annexes VII to XI on information requirements and general rules for adaptation was discussed at the REACH Committee. While voting is foreseen to take place in December 2020, the timelines for implementation will depend on the comments received and on further exchanges with the Member States. One national helpdesk pointed toward the impact the update of Annexes VII-XI will have on helpdesk work.

Concerning regulations amending Annex XVII to REACH, these include the adopted regulation as regards the restriction on diisocyanates, and the upcoming adoption (under scrutiny) for the regulations as regards the restrictions on: carcinogenic, mutagenic or reproductive toxicant (CMR) substances; substances in tattoo inks or permanent make-up; and lead in gunshot in or around wetlands. Pending draft regulations currently under discussion at the REACH Committee include the restrictions on: C9-C14 perfluorocarboxylic acids, their salts and related substances; polycyclic aromatic hydrocarbons in granules and mulches used as infill material in synthetic turf playing surfaces and in playgrounds; and N,N-dimethylformamide.

A regulation amending Annex XIV to REACH with respect to four phthalates (DEHP, BBP, DBP and DIBP), following the identification of additional intrinsic properties is currently at the drafting stage. Once published, this may trigger further review of granted authorisations or the need to re-assess finalised opinions (5-6 decisions/AfAs impacted) to uses of these phthalates. Granted authorisations may be reviewed in accordance with Article 61(2)(a) (due to changed circumstances).

A Commission Implementing Regulation was adopted (coming into force on 11 December) clarifying the duties placed on registrants to update their registration dossiers in line with Article 22 of REACH⁴². Regarding other implementing acts on REACH, the Draft Commission Implementing Regulation on applications for authorisation and review reports for uses of Annex XIV substances in the production of legacy spare parts and in the repair of articles and complex products no longer produced will be discussed in the upcoming REACH Committee.

Furthermore, due to a number of requests related to a postponement of the sunset date (4 January 2021) for uses of the Annex XIV substance 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPE) in the production of vaccines for COVID-19 purposes, the Commission is currently finalising an assessment and the outcome will be made available to the public soon.

Current and upcoming work on authorisation decisions by the Commission involves four adopted decisions and three upon adoption (Cr(VI)), three pending draft decisions under discussion at the REACH Committee (CTPht – first decision, TCE – first review report decision, diglyme) and a significant number of decisions at drafting stage (mainly OPE/NPE, but also CTPht, Cr(VI)).

Among the authorisation decisions upon adoption, it is worth to highlight the CTAC (Chemservice) authorisation decision, affecting a large number of downstream users, whose vote of the REACH

⁴² <u>https://eur-lex.europa.eu/legal-</u>

content/EN/TXT/?uri=uriserv:OJ.L_.2020.331.01.0024.01.ENG&toc=OJ:L:2020:331:TOC https://echa.europa.eu/-/deadlines-for-updating-registration-dossiers-clarified

Committee by written procedure ended on 23 October 2020, with a positive outcome. Riccardo ZORGNO highlighted the impact on the authorisation process of the landmark Court Judgment Case T-837/16 (Sweden vs Commission) on lead chromates of 7 March 2019⁴³ with regard to the requirement to submit a substitution plan also where suitable alternatives 'in general' are available (i.e. for other operators in the EU/EEA), but are not technically and economically feasible for the applicant.

As reported in details at the previous workshop, this new interpretation had a strong impact on the authorisation process and directly affects 12 applications for authorisation (including Cr(VI), DEHP, MOCA), for which the Commission sent requests to the applicants for submission of substitution plans with different deadlines until December 2020. The information received by ECHA will undergo consultation and the outcome of the assessment will be transmitted to the Commission as an addendum to the opinions. The Commission will subsequently take into consideration the addenda in deciding on whether to grant or not grant an authorisation with regard to those applications.

Regarding the actions from the second REACH Review⁴⁴, a multiannual development plan on Action 3 ('improving the workability and quality of extended safety data sheets'⁴⁵) will be discussed at the next CARACAL meeting in November 2020.

Lastly, the intermediate definition paper, triggered by the findings of another landmark Court case on acrylamide (C-650/15 P⁴⁶), was presented at CARACAL for consultation on 30 June 2020. The Commission is currently reviewing the received comments and further discussions will take place with the purpose to gather the necessary information for the Guidance update. One national helpdesk highlighted the significant implications the outcome of these discussions will have on industry.

1.2 Chemicals Strategy for Sustainability

Elena MONTANI (European Commission, DG ENV) introduced the Chemical Strategy for Sustainability⁴⁷. Her intervention is summarised under the agenda item 1.2 of the CLP Workshop.

2. Updates from ECHA

2.1 Registration of nanomaterials

Abdelqader SUMREIN (ECHA) presented the REACH requirements for nanomaterials as of 1 January 2020, covering all new and existing registrations for nanoforms when the total registration tonnage of the substance is above one tonne per registrant.

The presenter stressed the challenging timelines for ECHA and industry, and the way ECHA is preparing for that, updating the registration guidance and registration manual; updating IUCLID to include new fields for nanomaterial characterisation, information requirements (IUCLID 6.4); adapting the completeness check and dissemination processes; organising bilateral meetings with companies to understand challenges and give targeted advice; collaborating with Member States and national enforcement authorities (NEAs) for enforcement of registration, etc.

Abdelqader SUMREIN mentioned that 140 registrations covering nanoforms were received by ECHA so far, with a high rate of companies passing the technical completeness check (TCC). The presenter then explained the distinction between nanoforms and sets of nanoforms, the need for well-defined boundaries and the concept of `one nanoform-one dataset'.

ECHA has invested significant effort in the registration process, created a template in IUCLID guiding registrants towards a complete nanoform set justification and has provided direct support to individual companies failing TCC.

The new manual on 'How to prepare registration dossiers covering nanoforms'48 will be published

⁴³ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62016TJ0837</u>

⁴⁴ https://ec.europa.eu/growth/sectors/chemicals/reach/review is

⁴⁵ <u>https://echa.europa.eu/reach-review-action-3</u>

⁴⁶ <u>http://curia.europa.eu/juris/liste.jsf?language=en&num=C-650/15%20P</u>

⁴⁷ <u>https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf</u>

⁴⁸ Published on 28 October 2020, after the meeting: https://www.echa.europa.eu/documents/10162/22308

https://www.echa.europa.eu/documents/10162/22308542/howto_prepare_reg_dossiers_nano_en.pdf/5e_994573-6bf9-7040-054e-7ab753bd7fd6



reflecting lessons from previous submissions and improved advice; new Q&As⁴⁹ will be available on ECHA's website; and new nano guidance documents on human health and environment will undergo stakeholder consultation and are scheduled to be published in the third quarter of 2021 and 2022, respectively.

It was concluded that, despite clear legal obligations, scientific challenges remain. It is expected that in the upcoming years the challenges will shift from questions related to registration, towards questions on other REACH processes (e.g. evaluation). The HelpNet, along with other avenues for national experts to participate in giving advice (e.g. the NMEG) will prove important in addressing these challenges.

One HelpNet correspondent noted the potential link between the low number of registrations submitted to ECHA, showing that many nanoforms are still to be registered according to initial estimates made by ECHA, and almost no enquires being received by the national helpdesk on nanoforms. It was noted that the Forum members will address this matter in the meetings following the HelpNet events. Also, that information from nano registrations are disseminated⁵⁰ on ECHA's website, not necessarily the company name registering a specific nanoform.

Another correspondent informed that the national helpdesk received quite many enquiries at the end of 2019 and asked if the TCC lessons learnt can be shared with national helpdesks. In addition, she wished to address further questions⁵¹ to ECHA concerning recent HelpEx enquiries after the meeting.

The owner of question 17608 in HelpEx⁵² said that the presentation and the feedback provided by ECHA in HelpEx will help him to conclude if recovered nanoforms can rely on Article 2 paragraph 7(d).

Regarding bulk material already registered by a company upstream which is further transferred into a nanoform by a downstream user, it was clarified that a downstream user has the obligation to report information according to Article 38 in case he/she does not want to communicate the information upstream.

Participants appreciated the clear and comprehensive presentation given by Abdelqader SUMREIN, to which Anna DASZYNSKA and Jenny HOLMQVIST have contributed and welcome the support given by ECHA to national authorities responsible for the implementation and enforcement.

2.2 Evaluation

Laurence HOFFSTADT (ECHA) informed participants on new developments on ECHA's evaluation processes which took place since her previous presentation at the 14th Steering Group meeting in April 2019.

The presenter introduced the evaluation process according to the REACH joint action plan⁵³ 2019-2027 addressing REACH compliance; gave an update of evaluation achievements; and examples of helpdesk enquiries.

ECHA aims to screen all registration dossiers submitted by the 2018 deadline by:

- 2023 for substances registered over 100 tonnes per year; and
- 2027 for substances in the tonnage band 1-100 tonnes per year.

ECHA will have also performed a compliance check for all substances where data gaps prevent from concluding whether there is a concern, or the substance is of low priority for further regulatory action.

In line with ECHA's Integrated Regulatory Strategy, similar substances will be assessed in groups, with a target between 70 and 100 groups/year. For high tonnage substances (>100 tonnes per year), ECHA will conclude whether they are a priority for risk management, for data generation or currently of low priority for further action.

/qa/70Qx/view/scope/REACH/Nanoforms+of+substances

⁴⁹ <u>https://echa.europa.eu/support/qas-support/browse/-</u>

⁵⁰ For detailed information regarding principles of dissemination of information see the manual 'Dissemination and confidentiality under the REACH Regulation' available at: <u>http://echa.europa.eu/manuals</u>

 ⁵¹ Document submitted after the meeting available in S-CIRCABC at: https://webgate.ec.europa.eu/s-circabc/sd/d/ed5ad7fb-4383-4e20-b181-8723fa17ad3a/Comments_%202.1%20Nano_Germany.pdf
 ⁵² HelpEx ID 17608 on sameness of substance in relation to nanoforms and REACH Art. 2.7(d).
 ⁵³ REACH Evaluation Joint Action Plan

https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en/ 0003c9fc-652e-5f0b-90f9-dff9d5371d17



Laurence HOFFSTADT gave an update on the evaluation achievements, with a number of 50 Group Management Teams (GMT) processed so far, corresponding to 1 200 substances screened, 360 compliance checks performed and 300 conclusions not finalised due to dependency on other actions (e.g. ongoing data generation for a member of the group) and 721 tests requested in 2019.

ECHA's action plans for addressing the lack of compliance of REACH registration dossiers were explained in the webinar⁵⁴ of 26 November 2019.

Finally, Laurence HOFFSTADT introduced examples of helpdesk enquiries and support material prepared by ECHA (see the presentations slides⁵⁵ for detailed answers).

As a reminder, the following documents/links are provided below:

- Practical guides on <u>dossier</u> and <u>substance evaluation</u>
- Practical guide on information requirements and adaptations
- <u>Q&As</u> on ECHA website
- <u>Recommendations to registrants</u>
- <u>Dossier evaluation status</u> to monitor your substances
- <u>CoRAP</u>, <u>PACT</u> and other material for information on authorities' priorities and plans.

The following matters were further discussed and clarified:

- The grouping of substances is starting with an IT screening, then each group of substances is reviewed based on the structural similarity. In some cases, there might be slight variations in assessing if a substance would belong to the group or not, or if the group is complete and no substances were left out. The objective of the screening is to identify the best path to correctly regulate any substance in the EU. In this context one helpdesk questioned the wording of a 'preliminary RMOA' in the screening approach, as an RMOA (according to REACH) is developed much later during the regulatory processing of a substance or group of substances. Laurence HOFFSTADT clarified that the high-level similar approach needed to be understood, e.g. whether ECHA identifies a 'need for further EU risk management measures'.
- Ceasing the manufacture/import or downgrading the tonnage band has different consequences depending on whether the registrant/importer received a draft or a final decision from ECHA and when this decision was taken. These scenarios are addressed in the practical guides⁵⁶ e.g. <u>Registrant's guide – How to act in substance evaluation</u> and <u>How to act in dossier evaluation</u>.

2.3 Restrictions

Augusto DI BASTIANO (ECHA) presented the developments on the REACH Restriction process in 2020-2021, including ongoing work on restriction proposals currently in preparation and in opinion making, adopted RAC/SEAC opinions on restrictions, restriction intentions and other restriction activities.

More specifically, restriction proposals currently in preparation include lead chromates (Article 69(2)) and lead in ammunition and fishing tackle. Restriction proposals currently in opinion-making include intentionally added microplastics and PFHxA. In 2020, the RAC and SEAC committees have adopted opinions on restrictions on D4/D5/D6 in consumer and professional products, PFHxS in substances, mixtures and articles; five cobalt salts; skin sensitisers in textiles; calcium cyanamide; and formaldehyde. Still in the course of the year, restriction intentions have been notified to ECHA for PFAS in firefighting foams; PAHs and other substances in baby nappies; DMAC and NEP; Dechlorane plus; and BPA as an emission reduction measure for adhesives, residues, mixtures and articles⁵⁷.

Additional restriction activities that have taken place in 2020⁵⁸, concern the publication of investigation reports on lead and its compounds in consumer articles (entry 63) and PAHs in consumer articles (entry 50, paragraphs 5 and 6); a report on cadmium and its compounds in recycled PVC (entry 23) is under preparation and it is foreseen to be published in the next months. Furthermore, Article 69(2) screening is

⁵⁴ <u>https://echa.europa.eu/-/improving-the-quality-of-your-reach-registration-dossier-what-authorities-are-planning-and-how-you-can-prepare</u>

⁵⁵ Meeting documents are available for HelpNet members and observers in S-CIRCABC: Path:/CircaBC/echa/HelpNet/Library/02 Steering Group/HelpNet 15

⁵⁶ <u>https://echa.europa.eu/practical-guides</u>

⁵⁷ <u>https://echa.europa.eu/registry-of-restriction-intentions</u>

⁵⁸ <u>https://echa.europa.eu/completed-activities-on-restriction</u>



currently ongoing for several substances on the Authorisation List with regard to the presence of Annex XIV substances in articles and the risks associated to their use.

Concerning restriction Q&As, a general Q&A was published in 2019 on the meaning of articles in restriction entries (<u>Q&A 1564</u>). In addition, the sixth batch of Q&As is currently under finalisation. Main topics concern hazard classes, textile articles and clothing, applicable restrictions in textile and leather articles, use of NMP in production of articles. The seventh batch of Q&As is foreseen to be completed in 2021. This compilation will take into account helpdesk questions on restrictions in 2018-2020, enforcement issues from Forum and questions from industry and Member State competent authorities.

Lastly, ECHA web pages on restrictions were presented, including an interactive flow chart on ECHA's restriction process⁵⁹, a web page with a compilation of useful links⁶⁰ and content under the `chemicals in our life'/ `hot topics' web pages⁶¹.

HelpNet members and observers were invited to propose Q&As on restrictions to be included in the upcoming seventh batch and to provide any feedback on restrictions support material. It was also explained that ECHA has developed a quality management document to harmonise the approach of developing and updating Q&As on ECHA's website (including restriction Q&As) and that the national helpdesks will be informed before publication.

2.4 Impact of REACH restriction and authorisation on substitution in the EU

Giorgi KVATCHADZE (ECHA) presented the main findings of ECHA's report⁶² on the impacts of REACH restriction and authorisation on substitution⁶³ in the EU.

The report, based on a survey of 96 respondents, examines real-life impacts of REACH authorisations and restrictions on companies' substitution activities in terms of: main drivers for substitution, estimated cost of substitution, time required to switch to a substitute, barriers and challenges to substitution, benefits of substitution.

The REACH Regulation was found to be a significant driving factor for substitution with restriction (19 %) and authorisation (Candidate List/Annex XIV) (15 %) processes as the most significant triggers⁶⁴. The biggest challenges to substitution are mostly of technical nature (available/technically feasible alternatives), followed by economic and market barriers. Lastly, the key benefits of substitution were recognised as the reduction in emissions to the environment and in worker exposure.

The report is complemented by another report⁶⁵ on the implementation of ECHA's substitution strategy in 2018-2019 and focus in 2020-2021, which describes how ECHA has helped and intends to help companies overcome barriers to substitution.

The two reports aim to show how substitution is driven both by regulatory action and by encouraging companies in an indirect manner.

The representative of one national helpdesk asked about how non-regulatory drivers, such as customer demand, could drive substitution and how it is possible to raise awareness on such drivers. Giorgi KVATCHADZE noted that while customer demand is a significant factor to drive substitution, it is the increasing awareness of the customers with respect to the regulatory framework requiring the replacement of hazardous substances with safer alternatives that actually drives this demand.

The national helpdesks were invited to provide comments or feedback on ECHA's substitution report.

⁵⁹ <u>https://echa.europa.eu/restriction-process</u>

⁶⁰ <u>https://echa.europa.eu/information-restricted-substances</u>

⁶¹ https://echa.europa.eu/hot-topics

 ⁶² <u>https://www.echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf</u>
 ⁶³ <u>https://echa.europa.eu/substitution-to-safer-chemicals</u>

⁶⁴ <u>https://www.echa.europa.eu/-/restriction-and-authorisation-found-to-drive-replacement-of-harmful-</u> <u>chemicals</u>

⁶⁵ <u>https://www.echa.europa.eu/documents/10162/24152346/substitution_supporting_activities_en.pdf</u>



3. Topics proposed by ECHA and national helpdesks

3.1 Borderline cases between substances/mixtures and articles

Telmo Jorge VIEIRA PRAZERES (ECHA) talked about article definition⁶⁶ under REACH, the elements of the article definition (object, function, shape and surface, physical form and chemical composition), the substances in articles (SiA) guidance⁶⁷ workflow and examples of borderline cases.

Telmo Jorge VIEIRA PRAZERES presented the regulatory obligations triggered by the article definition and gave examples of objects and complex objects and the related Q&As published on ECHA website⁶⁸:

- objects with a physical form which are not articles: blasting grit, wax crayon, welding/soldering wire, permanent magnet (O&A 1292), coke electrode for the aluminium industry (O&A 1195)
- complex objects (assembled mechanically or joined using a substance/mixture)
- very complex and extremely complex objects.

The presenter concluded that the assessment on whether an object is an article under REACH needs to be done on a case-by-case basis after identifying the function of the object and generalisations should be avoided, because exceptions frequently exist.

Based on the examples included in the 'Guidance on requirements for substances in articles', Telmo Jorge VIEIRA PRAZERES then referred to particular steps of the workflow assessment:

- as defined in chapter 4.1 concerning whether an article should be considered an 'article with intended release of a substance/mixture' or not;
- under step 2, appendices 3 and 4 and published Q&As assessment of certain large (sub)groups • of objects with common features;
- step 6 of the workflow transition point from a substance/mixture to an article in a processing • sequence and the assessment of objects which are further processed;
- steps 4 to 5 of the workflow the substance/mixture in question is enclosed within the object (by • a container – which very frequently is a complex object); and that substance/mixture in question can be physically separated from the object; and
- step 2 of the workflow a clear conclusion cannot be reached when checking whether the shape, . surface or design of the object is more relevant for the function than its chemical composition, with reference to that substance/mixture in guestion.

Finally, the presenter described the implications of the ECJ judgement in case C-106/14. The Court analysed the concept of 'article' under Article 3(3) of REACH and its relevance for the duties to provide information under Articles 7(2) and Article 33 of REACH and concluded that in the case of complex articles the calculation of the 0.1 % w/w threshold must be made by reference to each component that gualifies as an 'article'.

The Chair opened the floor for discussion, mentioning that a dedicated workshop on borderline cases is scheduled to take place on 10 November 2020, where EU national helpdesks and experts from enforcement authorities are invited to discuss more concrete borderline cases.

Due to intensive discussions taking place within one helpdesk during the presentation, and different conclusions reached by the helpdesk on specific examples, they would like to send their comments⁶⁹ to ECHA in writing.

Discussion took place on the example burning fuse of a firework vs candle:

The function of the rocket fuse is to create/sustain an external flame. The chemical composition of the fuse acts as the combustible for the combustion. Because the chemical composition is more important, the fuse is regarded as a mixture.

https://echa.europa.eu/guidance-documents/guidance-on-reach

⁶⁶ REACH defines 'articles' as 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition'. ⁶⁷ Guidance on requirements for substances in articles:

⁶⁸ <u>https://echa.europa.eu/support/qas-support/browse/-</u>

[/]ga/70Qx/view/scope/reach/Requirements+for+substances+in+articles

⁶⁹ Comments submitted after the meeting available in S-CIRCABC at: <u>https://webgate.ec.europa.eu/s-</u> circabc/sd/d1a81d2b-1cae-4629-9df9-520e6b7c07af/Comments 3.1%20Borderline Germany.pdf



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- Candle is seen as a combination of a mixture and an article, with the wax (part of the mixture) and the wick (article). The function of the wick is to allow the wax to burn (secondary function). The main function of the wick is to not burn in order to allow the melted wax to sustain the light.

One correspondent referred to difficult questions in relation to the defence exception received by the national helpdesk and wished to know if any other national helpdesk received similar questions, or if they use the guidance⁷⁰ issued by the European Defence Agency (EDA) in replying to enquirers. Regarding the EDA guidance, the presenter clarified that the document reflects the views of the EDA participating Member States. ECHA has provided EDA, at their request, support to clarify specific issues that they were facing while developing the document.

ECHA explained the principles for deciding whether an object is an article or not, in accordance with the ECHA guidance documents. In some cases, the defence sector may decide to make their own assessment, whereas ECHA will make its own assessment concerning military or defence uses regarding ammunition and their components, when deemed necessary within the REACH regulatory processes (e.g. authorisation and restriction).

Participants confirmed that when receiving questions on borderline cases from their customers or the enforcement authority, they try to make their own assessment using the ECHA guidance documents and refer to ECHA whenever a solution cannot be found. Some would find it useful to have more examples given in the guidance, while others recognise that not all cases can be covered in such a document.

Telmo Jorge VIEIRA PRAZERES explained that more examples given would open more challenging discussions requiring significant resources allocated.

Closing of the REACH Workshop

The Chair listed the actions points 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 the participants to reply to the satisfaction survey which will be sent after the meeting and closed the REACH Workshop.

⁷⁰ <u>https://www.eda.europa.eu/docs/default-source/brochures/eda-member-states-common-position-on-ammunition-classification-under-reach---adopted.pdf</u>



Annex I – Agenda

Monday, 19 October 2020 15th HelpNet Steering Group meeting - WebEx session

Chair: Erwin ANNYS 15th HelpNet Steering Group meeting 11:00 1. Opening the Steering Group meeting 1.1 Opening by the Chair of the HelpNet 1.2 HelpNet 14 - follow-up of action points 1.3 Approval of the HelpNet 15 draft agenda 11:30 2. Updates from the HelpNet Secretariat 2.1 Approval of Handbook (ECHA, Elena BIGI) 2.2 Management of ECHA Q&As (ECHA, Peter SIMCIC) Discussion Break 45' 2.3 Visiting programme (ECHA, Viorica NAGHY) 2.4 The UK withdrawal from EU (ECHA, Jukka MALM) 2.5 Choosing our future (ECHA, Jukka MALM) Discussion 14:00 3. ECHA activities 3.1 Guidance activities, new procedure (ECHA, Erwin ANNYS) 3.2 Forum activities (ECHA, Maciej BARANSKI) Discussion Break 30' 3.3 Communication activities (ECHA, Johanna SALOMAA-VALKAMO) 3.4 EU Chemicals Legislation Finder (EUCLEF) (ECHA, Elisa LIRAS) 3.5 First ideas on the Chemicals Strategy for Sustainability (ECHA, Erwin ANNYS) Discussion 16:30 Conclusions of the day

16:45 **Closing the 15th Steering Group meeting**



Tuesday, 20 October 2020 BPR Workshop – WebEx session

Chair: Erwin ANNYS

BPR Workshop 11:00 **Opening by the Chair** 15' 11:15 1. Update on BPR hot topics 1.1 Update from the European Commission (DG SANTE, Ligia NEGULICI) Discussion 1.2 The UK withdrawal from the EU (ECHA, Camilla BUCHANAN) 1.3 Active substance action plan (ECHA, Carmen ESTEVAN MARTINEZ) Discussion Break 45' 13:30 2. Support and enforcement activities 2.1 Update from the Forum BPR Subgroup (ECHA, Nicola TECCE) 2.2 Development of BPR support material (ECHA, Claudio PUTZU) Discussion Break 30' 2.3 Cefic support activities by the European Biocidal Product Forum (EBPF) (Cefic, Camelia MIHAI) 2.4 A.I.S.E. support activities (A.I.S.E., Elodie CAZELLE) 2.5 Fecc support activities (Fecc, Simina DREVE) Discussion 15:45 **Conclusions** of the day 16:00 **Closing the BPR Workshop**

Wednesday, 21 October 2020 CLP Workshop – WebEx session

Chair: Erwin ANNYS

CLP Workshop

11:00	Opening by the Chair
11:15	1. Updates from the European Commission
	1.1 Updates on the implementation of CLP (DG GROW, Anna SCHUSTER)
	1.2 Chemicals Strategy for Sustainability (DG ENV, Elena MONTANI)
	Discussion
	2. Updates from ECHA
	2.1 Updates from CARACAL (ECHA, Ari KARJALAINEN)
	Discussion
	Break 60′
	2.2 Poison Centre Notification - support material (ECHA, Poison Centre team)
	Discussion
	Break 30'
14:30	3. Topics proposed by national helpdesks
	3.1 Classification and labelling of TiO2 and mixtures containing TiO2 (Germany, Anja KNIETSCH)

3.2 Overlapping legislation on electronic lighters (Ireland, Caroline WALSH)

3.3 Generation of new data under CLP (Bulgaria, Elena ZIDAROVA)

Discussion

15:30 **Conclusions**

15:45 Closing the CLP Workshop



Thursday, 22 October 2020 REACH Workshop - WebEx session

Chair: Erwin ANNYS

REACH Workshop

11:00 Opening by the Chair 10'

11:10 **1. Update from the European Commission**

1.1 Update on the implementation of REACH (DG GROW, Riccardo ZORGNO)

1.2 Chemicals Strategy for Sustainability (DG ENV, Elena MONTANI)

Discussion

11:55 **2. Updates from ECHA**

2.1 Registration of nanomaterials (ECHA, Anna DASZYNSKA, Abdelqader SUMREIN)

Discussion

Break 30'

2.2 Evaluation (ECHA, Laurence HOFFSTADT)

2.3 Restrictions (ECHA, Augusto DI BASTIANO)

2.4 Impact of REACH restriction and authorisation on substitution in the EU (ECHA, Giorgi KVATCHADZE)

Discussion

Break 30'

15:00 **3. Topics proposed by ECHA and national helpdesks**

3.1 Borderline cases between substances/mixtures and articles (ECHA, Telmo Jorge VIEIRA PRAZERES)

Discussion

16:00 Conclusions

16:15 Closing the REACH Workshop



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Annex II - Action points

15th HelpNet Steering Group meeting

No	Action	Agenda item	Responsible	Due date	Status
1.	Launch a written procedure for the approval of the <u>HelpNet Handbook.</u>	2.1	ECHA, NHDs	6-20 November 2020	Closed
2.	Inform national helpdesks (bi-monthly) on ECHA's Q&As updates.	2.2	ECHA	-	Ongoing
3.	Share <u>Q&A editorial rules</u> .	2.2	ECHA	4 November 2020	Closed
4.	Send your feedback on Q&A management to the HelpNet Secretariat (<u>help-net@echa.europa.eu</u>) or to ECHA Q&A team <u>qa-update@echa.europa.eu</u> .	2.2	NHDs, observers	-	Open
5.	Reflect on additional training sessions (e.g. HelpEx), workshops, bilateral/trilateral virtual meetings upon request.	2.3	ECHA, NHDs, observers	-	Ongoing
6.	Keep HelpNet informed on the progress of the UK withdrawal from the EU.	2.4	ECHA	Q1 2021	Closed
7.	Keep HelpNet informed on the progress of MFF - multi-annual activity and resources planning.	2.5	ECHA	When available	Open
8.	Use SCIP communication materials if providing advice on the REACH requirements for recovered waste substances: <u>webinar</u> , animation, leaflet, infographic, social media posts: <u>https://echa.europa.eu/scip</u> .	3.3	NHDs, observers	-	Open
9.	Contact ECHA if interested to write a nanopinion <u>euon.echa.europa.eu/nanopinion</u> or use enforcement communication packages.	3.3	NHDs, observers	-	Open
10.	Promote <u>EUCLEF</u> regulatory support service, provide feedback to ECHA.	3.4	HelpNet	-	Open



11.	Share the link to the European Commission website on Chemicals Strategy:	3.5	ECHA	November	Closed	
	https://ec.europa.eu/environment/strategy/chemicals-strategy_en.			2020		

BPR Workshop

No	Action	Agenda item	Responsible	Due date	Status
1.	Share the link to national rules applying to biocidal products placed on the market according to Art. 89 of the BPR List of national websites on transitional measures (BPR Article 89) published on ECHA website at: https://echa.europa.eu/support/helpdesks/	2.1	ECHA	November 2020	Closed
2.	Send suggestions for the Covid-19 webpage update through the ECHA contact forms, choosing the option 'ECHA website': https://comments.echa.europa.eu/comments cms/Contact Other.aspx	2.1	NHDs	-	Closed

CLP Workshop

No	Action	Agenda item	Responsible	Due date	Status
1.	Agree on how to translate the guide on TiO2, prior to sharing it with the HelpNet.	3.1	ECHA, German helpdesk	November 2020	Closed
2.	Run a written procedure to collect replies to questions from the Irish helpdesk.	3.2	ECHA	6-20 November	Closed



Minutes 20 January 2021

REACH Workshop

No	Action	Agenda item	Responsible	Due date	Status
1.	Send any clarification questions on the update given by the representative of the European Commission, <u>Riccardo ZORGNO</u> .		NHDs	Q4 2020	Closed
2.	Comment on HelpEx 17608 (NL) (nanoforms & recovered substances/REACH Art. 2(7)(d)) following the feedback provided by ECHA. Based on the comments received, ECHA will re-discuss the case with its legal experts.	2.1	ECHA, NHDs	By 30 November 2020	Closed
3.	Inform NHDs on publication of ECHA's Manual <u>How to prepare registration</u> dossiers covering nanoforms.	2.1	ECHA	9 November 2020	Closed
4.	Provide suggestions for restriction Q&As (7^{th} batch) and feedback on restrictions web pages/ support material.	2.3	NHDs	By 15 December 2020	Closed
5.	Send any questions or feedback on ECHA's <u>report</u> on substitution/ presentation to <u>Giorgi.KVATCHADZE@ext.echa.europa.eu</u> .	2.4	NHDs	Q4 2020	Closed
6.	Provide comments on the substances in articles (SiA) borderline cases presentation.	3.1	German helpdesk	28 October 2020	Closed
7.	Participate in/contribute to the HelpNet Workshop on Borderline cases on the article definition scheduled on 10 November 2020.	3.1	NHDs	10 November 2020	Closed



Annex III - List of participants

Members of HelpNet

Country	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
Austria	Barbara WETZER	Х		Х	х
	Erich NEUWIRTH			Х	х
	Jérôme COLSON	Х	Х		
Belgium	Daphné HOYAUX	х			х
Bulgaria	Elena ZIDAROVA			Х	
Croatia	Romana GRIZELJ	Х	Х	Х	х
	Ivana VRHOVAC FILIPOVIC	х	Х		
	Silva KAJIĆ	Х		Х	х
	Zdravko LOVRIĆ	Х		Х	
	Irena Zorica JEŽIĆ VIDOVIĆ		Х		х
Cyprus	Andreas HADJIGEORGIOU		Х		
	Maria ORPHANOU	X		х	х
	Maria PALEOMILITOU	x		х	
Czech	Jarmila SLÁDKOVÁ	X		х	х
	Jan KOLAR	х			
Denmark	Lone KAERGAARD		х		
	Ditte PALUDAN	Х		Х	
	Iryna MARCUSLUND	Х	Х		
	Maria THESTRUP JENSEN	х			
	Toke THOMSEN				х
Estonia	Anna AMELKINA	х			х
	Aigi LAHE	х		х	
	Riina LAHNE	х	Х		
Finland	Hannu MATTILA	х	х		
	Mervi ASSMANN	х			х
	Jussi OLLIKKA	Х		Х	
	Pauli KÄRKKÄINEN	х		х	
	Sari TUHKUNEN	x			х
France	Stephanie COPIN				х
	Nathalie HAYAUD	х		х	
Germany	Anja KNIETSCH			Х	
	Juliana REY		x		
	Suzanne WIANDT	x			x



Country	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
Greece	Panagiota SKAFIDA	x	x	x	x
Hungary	Tamas KOVACS	x		x	x
	Anna TÜSKE	x	x		
	Nikoletta MAROSVÖLGYI	x		x	x
Iceland	Björn GUNNLAUGSSON	x			
	Hafdís Inga INGVARSDÓTTIR		x		
	Fifa KONRADSDOTTIR			x	
	Ísak Sigurjón BRAGASON				х
Ireland	Caroline WALSH			x	
	Donal LYNCH		x	x	
	Majella COSGRAVE	x		x	x
Italy	Sonia D'ILIO	x	x	x	
	Francesca GIANNOTTI	x			x
	Francesca CARFÌ	x			х
	Maria ALESSANDRELLI	x	x		
	Sabrina MORO IACOPINI	x			x
Latvia	Elīna LAZDEKALNE			x	х
	Irbe SEDLENIECE	x	x		
Lithuania	Jurgita BALČIŪNIENĖ	x		x	x
	Agnė JANONYTE	x		x	x
	Beata VOLUJEVIČ	x		x	x
	Evelina BARONIENE		x		
Luxembourg	Laurene CHOCHOIS	x		x	
	Oona FREUDENTHAL	x			x
Netherlands	Evan BEIJ	x	x		
	Femke AFFOURTIT			x	
	Thijs de KORT	x			х
	Peter van IERSEL	x		x	x
	Lizette WELGRAVEN		x		
Norway	Cecile BLOM	x			x
	Bodil FAARLUND			x	
	Solveig AAMODT	x	x		
	Marie DAHLBERG PERSSON			x	
	Abdulqadir SULEIMAN			x	x
Poland	Łukasz BELKIEWICZ	x	x		
	Krzysztof DOMAŃSKI	x		x	x



Country	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
Poland	Monika WASIAK-GROMEK	x		x	x
Portugal	Fátima de Maria ARAÚJO				x
	Isabel LAGINHA	x		х	x
Romania	Nicoleta CAROLE	x		х	x
Slovakia	Martina KOKAVCOVA	x		x	x
	Jana CHMELIKOVA	x	x		
	Lucia MURANIOVA	x			
Slovenia	Tatjana HUMAR JURIČ	x		x	
	Anja MENARD SRPČIČ	x			x
	Marta PAVLIČ ČUK	x	x		
	Simona FAJFAR			x	
Spain	Elena Maria SANCHEZ DIAZ	x		x	x
	Laura ZAMORA NAVAS	x		x	x
Sweden	Anneli RUDSTRÖM	x	x		
	Karin ALKELL	x			x
	Helena KRAMER	x			x
	Susanna NORRTHON RISBERG	x		x	
	Jenny VIRDARSON	x			

European Commission

DG	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
DG ENV	Elena MONTANI			х	х
	Sofoklis STRATAKIS			х	
DG GROW	Anna SCHUSTER			х	
	Ricardo ZORGNO				х
DG SANTE	Ligia NEGULICI		x		



Candidate countries observers

Country	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
Montenegro	Nevena BOGAVAC	x	x	х	
	Tatjana MUJICIC		х		
Serbia	Snežana JOKSIMOVIĆ	x			х
	Biljana MILENKOVIĆ		х		

Third Country observers

Country	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
Switzerland	Markus HOFMANN	x		х	
	Olivier BLASER		х		

Industry observers

Organisation	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
A.I.S.E.	Dominic BYRNE			x	
	Elodie CAZELLE		x		
	Jan ROBINSON	x			
Cefic	Amaya JÁNOSI	x			
	Camelia MIHAI		x		
	Liisi DE BACKER			x	
Fecc	Simina DREVE		x		
IMA Europe	Roger DOOME			x	
ORO	Kevin HOBAN			x	
	Tanja SAGERMANN				x

ECHA staff

ECHA/unit ⁷¹	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
A0	Jukka MALM	х			
A1	Adam ELWAN	x			

⁷¹ <u>https://echa.europa.eu/about-us/who-we-are/organisation</u>



ECHA/unit ⁷¹	Name, surname	HelpNet Steering Group meeting	BPR Workshop	CLP Workshop	REACH Workshop
A1	Johanna SALOMAA VALKAMO	x			
A2	Anisa KASARUHO		х	х	х
	Anna-Liisa PIKKARAINEN	x	x	х	x
	Carmen KLAUSBRUCKNER	x	х	х	х
	Christina LOUKOU	x	x	х	x
	Elena BIGI	х	х	х	x
	Erwin ANNYS	х	x	х	х
	Gary WATKINS				х
	Helena JARNSTROM	х			
	Maciej BARANSKI	x			
	Malgorzata SZKLAREK	x		х	х
	Nicola Tecce		x		
	Olena KRYCHEVSKA	x			
	Pedro ROSELLO VILLAROIG	x		x	
	Peter SIMCIC	x			
	Roxana BROASCA	x	x	x	x
	Viorica NAGHY	x	x	x	x
A3	Claudia RIMONDO			x	
	Daniele APE			x	
	Heidi RASIKARI			x	
	Javier SANCHEZ SAEZ			x	
	Tiago PEDROSA				x
A4	Abdelqader SUMREIN				x
	Anna DASZYNSKA				x
	Elisa LIRAS	x			
B4	Outi TUNNELA			x	x
	Telmo Jorge VIEIRA PRAZERES				x
C1	Ari KARJALAINEN			х	
C2	Amaia RODRIGUEZ-RUIZ				х
C3	Laurence HOFFSTADT			x	
D1	Carmen ESTEVAN MARTINEZ		x		
	Claudio PUTZU		x		
D3	Augusto DI BASTIANO			x	
D4	Giorgi KVATCHADZE				х
E1	Jenny HOLMQVIST				x
E2	Camilla BUCHANAN		x		
R3	Kostas ANAGNOSTAKIS		x	x	