HELPNET 18 MEETING MINUTES

Table of Contents

REACH Workshop

Opening by the Chair

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

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

1. Morning session

1.1 Update from the European Commission

Miriam STAHLHACKE (European Commission, DG GROW) gave an overview on legislative developments, in particular the Amendment to Annex XIV and XVII of REACH, authorisation decisions, court cases and the REACH revision.

Commission (COM) outlined the recent Annex XVII updates as follows:

The restriction of lead and its compounds in PVC has been adopted.

There have been favourable opinions from the REACH Committee on the following proposed restrictions:

- formaldehyde and formaldehyde releasers, and
- microplastics

The REACH Committee supported the update of Appendices 1-6 of Annex XVII which will list substances newly classified as CMR 1A and B subject to the restrictions of entries 28-30.

Additionally, COM is currently working on 3 new proposed restrictions:

- Skin sensitisers in textiles,
- PFHxA, and
- D4, D5 and D6 in leave-on products (ready to launch inter-service consultation).

Finally, the references to the standards in support of restriction entry 27 (nickel and its compounds) has been published in the Official Journal on 3 March.

Further, updates to Annex XIV were introduced:

There have not been new substances added to Annex XIV since the October HelpNet 17 meeting. ECHA has sent the 11th recommendations for inclusion in the Authorisation List in April 2023.

COM has drafted a regulation amending entry 4c following amendment of the medical devices regulation in order to reflect the extension of deadlines in this regulation. The proposed Annex XIV amendment will align deadlines in REACH entry 4c. The draft proposal was presented by COM in the last REACH committee meeting and the vote by written procedure is being

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

launched.

Many applications for authorisation, many of them for the use of chromates and OPE, have been received and several have been approved. COM presented the list of granted applications since the REACH Workshop which took place in October 2022 and the list of applications for authorisation to be discussed in the upcoming REACH committee meeting in June 2023.

COM then presented the court case C-144/21 annulling Commission Decision C(2020) 8797 partially granting an authorisation for certain uses of chromium trioxide. The consequences of this decision are under analysis by the EU Commission. Case T-868/19 requesting an annulment of Commission Implementing Decision of 16 October 2019 (C(2019)7336 final) on the compliance check of a registration of dimethyl ether (DME) was dismissed in its entirety.

COM ended the presentation by providing updates about the REACH revision. The current proposal timing aims at having a Commission proposal ready by Q4 2023.

The main changes highlighted were as follow:

- Revision of the information requirements for registration
- Introduction of a mixture assessment factor (MAF) to address the combined exposure to different substances.
- ECHA will be given a mandate to develop harmonized electronic formats for safety data sheets.
- Strengthening the 'no data no market' principle by allowing for the revocation of registrations
- Strengthening of control and enforcement
- Reform of authorisation and restriction processes: the restriction process is deemed too slow to address new challenges such as endocrine disruptors or persistent substances, and the authorisation process is seen as too burdensome. There is a need for enabling a faster decision process for both regulatory measures which shall be achieved, inter alia, through the extension of the Generic Approach to risk management, the introduction of the essential use criteria and a review of the current assessment of alternatives.

Discussion

NHDs informed the representative of the Commission that they receive questions related to the court decision on case C-144/21 annulling the authorisation for certain uses of chromates. It is noted that industry panics, as they need to make important decisions with heavy financial consequences. It is crucial that NHDs can answer these concerns from chromates users. There is a need to address these concerns in Q&As.

Miriam STAHLHACKE responded that the analysis of this judgment is a high priority and meetings are ongoing involving the legal services to determine how to proceed with the impacted authorisations in the future.

One correspondent welcomed the information that ECHA will be given a mandate to develop electronic formats for safety data sheets, as this is a topic generating many questions in general.

Action points

AP 1: The European Commission will update the HelpNet on the impact of the CTAC AfA annulment

AP 2: ECHA will share the link of the Forum enforcement project of authorisation - REACH-EN-FORCE-9 (REF-9) and presentations of the workshop.

1.2 Updates on the guidance for intermediates

Augusto DI BASTIANO (ECHA, Risk Management I Unit) gave an update on the ECHA guidance for intermediates (link) that was published in December 2022 to include the conclusions of the European Court of Justice (ECJ) judgment on the acrylamide case (C-650/P 15). In 2017, the ECJ decision on the acrylamide case rejected the interpretation of 'intermediate' status of a substance based on the main purpose of the use and set new requirements for the definition of intermediates. This triggered the need to update the guidance. A new proposal was prepared by the EU Commission and ECHA. In 2020, CARACAL rejected this joint proposal. In 2021, the EU Commission concluded that the legal text had to be clarified and ECHA was tasked to update the guidance. The main changes in the guidance were presented, i.e., the new definition for intermediates based on the three conditions imposed by the Court, and the new examples on how to assess the fulfilment of those conditions.

Discussion

One NHD noted that the process to review this guidance did not involve a Partner Expert Group (PEG), and that the update involved only ECHA and the Commission. As the initial proposal (joint ECHA/Commission position paper) was rejected at CARACAL, the NHD asked whether the guidance update was put forward at CARACAL before its publication. They also noted that one example from the initial guidance was deleted from Appendix 4 of the updated guidance (the use of chromates in plating applications). The NHD emphasized the need to onboard comments from the helpdesk when guidance documents are being reviewed. They also asked for clarification on how helpdesks could put forward their comments.

ECHA clarified that the initial idea was to first create a position paper and set up some principles. However, no agreement was ever reached between the Member States on this proposed position paper. As a result, the Commission decided that a change to the legal text was needed, and asked ECHA for a light update of the guidance in the meantime. ECHA also confirmed that the deleted example of the use of chromates used for chrome plating, which was included in previous versions of the guidance, is still valid and confirmed that this use is not to be considered an intermediate use.

Another NHD asked about the possible types of registration dossiers and how this will continue to be handled in REACH-IT. The NHD also asked about the exemption from authorisation for intermediates and whether this continues to apply. ECHA clarified that there are three different types of registration dossiers: intermediate registration under strictly controlled conditions (SCC), full registration, and "combo dossier" containing a certain amount of the substance registered as an intermediate under SCC and another amount registered as a full registration. Exemption from authorisation for intermediates is confirmed for all intermediates, regardless of the conditions of use. As a result, this exemption also applies to the intermediates not necessarily used under SCC. No intention to change this exemption has been shared in the review of the legal text, but there is an intention to clarify how intermediates should be used.

One NHD raised the issue that today, an operator can purchase a substance, use it as an intermediate, although there was no specific containment until the time they receive the substance. ECHA acknowledged that this is one of the reasons motivating the clarification of the legal text, and that the Commission confirmed that the requirement for containment must apply for the whole life cycle of the substance. This should apply for the whole supply chain, even in the case of import.

The Chair of the HelpNet provided some information on how the responsibility of the guidance documents have been shared among the different units in ECHA and suggested as an action point to share with the HelpNet information on the different processes to update ECHA guidance documents, which should also clarify how helpdesks could put forward their comments.

Action point

AP 3: ECHA will share the guidance process document with HelpNet members.

1.3 Restriction: Per-and polyfluoroalkyl substances (PFAS) restriction proposal

Michael GMEINDER (ECHA, Risk Management Unit) gave an introduction to the restriction process and the current status of the restriction proposal for per- and polyfluoroalkyl substances (PFAS). REACH restrictions can be seen as safety net where other REACH and EU processes cannot adequately control the risks posed by chemicals. A Member State (or a group of Member States), or ECHA at the request of the European Commission, can start the restriction procedure. The PFAS restriction proposal was prepared jointly by the national authorities of Germany, the Netherlands, Denmark, Norway and Sweden (the Dossier Submitters). The European Commission will take a balanced view of the identified risks and of the benefits and costs of the proposed restriction and the final decision is taken in a comitology procedure with scrutiny involving the Member States and the European Parliament.

Jenny IVARSSON (Dossier Submitters, KEMI) continued with an overview of the restriction proposal, including the definition, concerns and functions of PFAS, the sectors of use and the associated tonnages and emissions. The Dossier Submitters assessed two restriction options. One of which is a full ban of the substances, and the other corresponds to the proposed restriction, i.e., a ban with use-specific (mainly time-limited) derogations. The need for an EU-wide restriction of PFAS based on the identified risks was highlighted and it was underlined that this proposal is an appropriate measure to address these risks within a reasonable timeframe.

Discussion

One NHD asked if the Q&As published from the online information session are available only in English and whether the questions received by ECHA on this restriction proposal are responded to by ECHA or re-directed to the National Helpdesks. ECHA clarified that answers to questions relating to the restriction process are answered by ECHA, while questions on the content of the restriction proposal are referred to experts from the 5 national authorities that prepared the restriction proposal (Dossier Submitters). The Q&As from the online information session are only made available in English.

Another NHD noted that they are receiving questions from companies about alternatives to PFAS, given that they will have to consider this in their investment plans and purchase planning.

ECHA noted that the Dossier Submitters compiled a list of alternatives for the different sectors assessed, taking into account the information that was available when preparing the Dossier. This has been published together with the Annex XV report as an appendix (Appendix E2) on the ECHA website. Further information on alternatives may become available through the ongoing six-month consultation on the Annex XV report.

One correspondent asked how the concentration limits should be assessed for complex articles, for example air conditioning devices in cars, which include components that contain a combination of PFAS, PVC and TiO_2 substances.

ECHA highlighted that the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) are evaluating all the information contained in the Annex XV report together with information that is submitted during the six-month consultation. Furthermore, it was clarified that a second batch of Q&As on content-related questions raised during the online information session on the PFAS restriction proposal will be published soon and it may help to clarify aspects of this question.

One NHD asked the meaning of the statement in the presentation that 3 of the 11 proposed 5-year derogations are marked for reconsideration. Furthermore, the NHD asked if there was a possibility to include additional derogations.

The Dossier Submitter representative noted that for derogations that are marked for reconsideration in the restriction proposal there are some indications that a derogation could potentially be warranted but, as it stands, the available evidence is considered insufficient to propose a derogation. Therefore, industry is encouraged to submit additional information during the ongoing six-month consultation to justify the need for a derogation.

Another NHD asked whether they should recommend companies to provide more information about all the uses and not only for the uses for which there are derogations marked for reconsideration.

The Dossier Submitter representative emphasized that industry should submit any relevant and substantiated information they may have, not limited to the potential derogations which are marked for reconsideration. Nevertheless, the potential derogations marked for reconsideration do indicate specific areas where additional information would be appreciated.

ECHA added that while the Dossier Submitters have identified in the restriction dossier specific areas for which further information is sought, RAC and SEAC will evaluate the full proposal and provide their opinion on which proposed derogations are considered justified, considering the information in the restriction dossier and the comments received during the consultation.

1.4 Requirements for nanoforms in the safety data sheet – Ideas Jam

ECHA introduced the Ideas Jam items: The speaker introduces the topic. Participants then have about 15 minutes to discuss the topic in groups of approximatively 5 to 7 people, and later report on their contributions in the plenary.

Anja HACKMANN from the German helpdesk (BAuA[2]) presented the topic "requirements for nanoforms in the safety datasheet". The presentation provided some background information, an overview of the legal requirements, and described the four FAQs proposed by the German helpdesk on this topic. National helpdesks have frequently received questions on safety data sheets and identified the need to clarify some aspects and in particular requirements for information on nanoforms to be reported in the SDS. The German national helpdesk had proposed four FAQs following HelpEx discussions on this topic, and those FAQ proposals were still under review by ECHA legal experts. The objective of this Ideas Jam session was to clarify the requirements for nanoforms in the SDS, discuss the FAQs already proposed by the German NHD, and identify whether additional FAQs or support material would be needed on this topic.

Discussion

One group reported that none of their members ever received questions on the topic of nanoforms within the SDS. This group also discussed whether, in the case of a nanoform being dissolved in a mixture, it might be possible to still recover the nanoform after, e.g., evaporation of the solvent and, if so, whether information on the nanoform would still need to be provided based on a strict reading of the legal text. ECHA pointed out that it was not yet clear how the enforcement of the new requirements for nanoform in the safety data sheet would work and referred to the REACH enforcement project REF-11[3] where different views on how to approach the nanoform data in the safety data sheet had been shared during the training.

[2] The German Federal Institute of Occupational Safety and Health

[3] REF-11 mandate and timeline available at: 9e3464ba-d06e-cb99-c649-0abc55484ced (europa.eu)

Another group discussed the dissolution of a nanoform in a mixture and how it was possible to be sure that the nanoform was fully dissolved. Because of the uncertainty around this aspect, information on the nanoform would still need to be provided in the SDS. In addition, one NHD reminded that much more toxicological information and data on nanoforms were required to properly address their hazards.

Another group highlighted the possibility that the outcome of the REF-11 project would lead to a need to review or expand the current support material available on the topic. The NHDs from this group also stated that they had not received questions on the topic so far, but this may change after the REF-11 project was completed.

One group praised the leaflet on nanoforms developed by the German NHD and published on their website. The group highlighted the usefulness of developing a FAQ describing where to put the nano-specific information in the SDS and the exposure scenarios.

Finally, the Chair clarified that, at the end of each enforcement project, a report was published with recommendations. Certain parts of this report were also made available and translated in the languages of accessing countries.

2. Afternoon session

2.1 Updates on monomer and polymers' guidance

Laszlo MAJOROS (ECHA) outlined the updates that have been introduced in ECHA's Guidance for monomers and polymers after the Board of Appeal (BoA) decision on case A-001-2020 on the registration obligations for importers of polymers. The main change to the description of registration obligations is related to the obligation to register the monomer by the manufacturer or importer of a polymer. The decision of the BoA's means that the monomers and other substances that have reacted to form the polymer substance only need to be registered if the conditions set out in Article 6(3) are met. Another change is related to the calculation of registration tonnages of monomers ending up in the final polymer as a reacted substance. Example 6 of the guidance has been slightly modified in order to address these changes. Furthermore, the information that registrants of monomers must include in a registration chemical safety report has been updated and a new section added on 'Registration Chemical Safety Report'. ECHA updated the guidance in February 2023 and published it on the ECHA website.

Discussion

One NHD mentioned that one of the changes in the guidance is related to the polymer importers in which the CSA would stop at hazard characterization (as no uses need to be assessed). This would mean that HelpEx ID 2045 which is currently marked unsolved, could be answered with a final reply. ECHA proposed to check with the internal experts if it is needed to reopen this HelpEx question based on revised Guidance for monomers and polymers and suggested it as an action point.

Another participant asked if the requirements for reacted monomers will change if the polymers need to be registered after the REACH review. ECHA responded that there is not an answer for the question yet as the proposal for the REACH review is not available. Currently the discussion is about the notification obligations for all polymers placed in the market and potential registration of groups of polymers requiring registration.

Action point

AP 4: ECHA will check if there is a need to reopen HelpEx ID 2045 based on revised guidance for monomers and polymers.

2.2 Waste legislation case study – Ideas Jam

Simona FAJFAR (Slovenian helpdesk) presentation focused on two cases in which there is overlap between the Waste legislation and REACH.

The first case was about fly ash in which 3 sites (thermal plants) have registered the substances under REACH. Two scenarios were presented. Under the first one, the fly ashes are considered as side products (by-products) while under the second case, the fly ashes are encoded as waste and handed to a third company which is a waste collector.

The second case was about foundry sands, which are products found in nature (silicate mixed with clay) and are exempted from registration obligation under REACH. Those sands are used in the foundry industry by a company. After their use, they contain more than 99% foundry sands plus impurities, and they may be contaminated with hazardous chemicals. These sands are sold as construction materials, for further use after a cleaning process at the same site. Under this scenario, the end of waste criteria are met when these foundry sands are sold as construction material. The company issues a certification of a construction material before it is used in which it claims that there is no migration from the material considering it safe to use.

Discussion

One group noted that by-products are regulated by two legislations: the Waste Framework Directive (WFD) and the REACH regulation. It was also noted that some Members States recommend that all materials are registered while some other Member States not. Furthermore, it was discussed that according to the WFD, the owner and/or producer can decide how to classify the material (either as waste or as a substance).

Another group noted that it is important to know the source of the ashes as they are not uniform and well-defined substances. In this context, it is difficult to register it as such.

Finally, the chair noted that the potential relation with waste of the foundry sands need to be further discussed as these are regarded as natural substances which are extracted from Earth.

2.3 Applicability of Article 2(7)(d) exemption – Ideas Jam

Suzanne WIANDT from the German helpdesk (BauA)[4] and Amandine JOMIER (ECHA) gave a joint presentation on, respectively, BAuA's and ECHA's views on the scope of Article 2(7)(d) exemption, and the conditions for recovery operators to benefit from the exemption. The case presented was the following:

A substance has been registered as an on-site isolated intermediate (Art.17) or transported isolated intermediate (Art.18). The substance is then recovered in the EU so that the substance resulting from the recovery is chemically the same as the one previously registered (Article 2(7)(i)), and information required by Article 31 or 32 is available to the recovery operator (Article 2(7)(ii)). However, the recovered substance no longer meets intermediate requirements. Can the recovered substance benefit from the exemption provided for by Art.2(7)(d)?

The German national helpdesk highlighted that the only requirement provided for by Article 2(7)(i) was for the substance to have ever been registered, regardless of the information requirements fulfilled at the time of the registration or the ongoing validity of the registration when the recovery takes place. As far as information about the substance was concerned, the German NHD underlined that the legal text refers to Articles 31 and 32 of REACH, so that information must be available to the recovery operator, but it does not directly refer to information to be provided in the registration. On the other hand, ECHA sought, first of all, to

[4] Federal Institute of Occupational Safety and Health

separate the issue of the information requirements applicable to the registration (which determine the information already provided to ECHA about the substance) from the issue of the validity of the registration over time (which is currently under consideration in connection with the placing on the market or use of substances). As far as information requirements for registration purposes were concerned, ECHA was of the opinion that the correspondence between the information requirements for the registration of the initial substance and those relevant to the substance resulting from the recovery is essential for the latter to benefit from the exemption. This meant that, if the initial substance were registered as an isolated intermediate under strictly controlled conditions, the recovered substance had to fulfil all requirements for intermediates under the same conditions to benefit from the exemption from registration.

Other similar scenarios were presented, such as in the case of differences in tonnage bands (when recovered volumes are above the registered volumes), or in the forms of the substance (e.g., when the recovered substance is a nanoform, whilst the registration only covers the non-nanoform of the substance). The NHDs were then asked to share their views and interpretation on the scope of Article 2(7)(d) exemption and indicate whether they had received similar questions and if they saw the value of developing a FAQ on this topic.

Discussion

One group questioned the actual possibility to recover an intermediate without missing the conditions that make a substance such and asked for a real-life example of a recovered intermediate. They also mentioned that several issues related to this topic had been raised during the FORUM project on recovered substances.

Another group stated that, although this topic may refer to exceptional situations, it remained important to provide clarity. One correspondent insisted on the fact that the legal text referred to Articles 31 and 32 REACH but not directly to information to be provided in the registration. The correspondent insisted ~~about~~ on the fact that the legal text was not clear enough to develop a FAQ, as the FAQ would need to follow the legal text and not much could be said. They noted that this lack of clarity may be tackled by the REACH review. They also noted that this question had been asked in HelpEx and several countries informed having received analogous questions in the past. However, no harmonised reply had been provided so far.

Another group reported that they had not received this question recently but may have had in the past. They believed that ECHA's interpretation was the most appropriate one, but that the German interpretation was more in line with the current legal text. They supported the idea to try to develop a FAQ; however, they noted that it would be difficult to go beyond what was in the legal text. They also questioned the possibility to recover an intermediate, or to recover a substance at a tonnage band higher than the tonnage band at which the substance had initially been registered.

ECHA stated that, when the legal text led to problems of interpretation, the interpreter could not stop at a literal reading of it and should rather strive to reconcile the latter with the objective pursued by the legislation. The primary objective of REACH is ensuring a high level of protection of human health and the environment, as expressed in the Registration title, whose purpose is to gather information on the substances being manufactured or imported in the Union as a basis to implement possible risk management measures ('no data, no market'). As a result, if no information on a recovered substance is available because, e.g., this was registered as an intermediate in accordance with Article 17 or 18, or because a different form of the same substance was registered, exempting the recovered substance from registration would run against the primary objective of the legislation.

ECHA further clarified that, as also specified by the European Court of Justice, the term 'intermediate' referred to the intermediate use of a substance. Therefore, recycling an

intermediate means recycling a substance for an intermediate use.

One correspondent responded to this statement from ECHA by stressing that they are well aware of the objectives of REACH and would not want to be implicated that they would not follow these objectives when using the legal text as a basis for answering the questions on Article 2 (7)(d).

The Chair noted that the topic of recovery and recycling remained relatively marginal at the moment, but the number of questions related to chemical recycling would continue to grow in the future. The Chair also reminded that Enforcement authorities raised the issue of the interpretation of Article 2(7)(d) to the European Commission, and this might be considered in the REACH review.

Finally, one correspondent highlighted that they received questions on the topic of recovered substances, but mainly from a substance identity and substance sameness perspective. As recovered substances are often mixtures or UVCB substances, assessing substance sameness in this context can be very difficult. The Chair acknowledged the importance of this element too, and this was noted as a topic to be discussed at a future REACH Workshop.

Action point

AP 5: HelpNet Secretariat will include as a topic for the next REACH workshop in November 2023: Substance sameness in the context of recovered substances.

2.4 Grouping of substances – challenges identified

Amaya JANOSI (Cefic) introduced the industry perspective on the grouping approach followed by ECHA and Member States and the challenges encountered.

Substances grouping is conducted within different frameworks: communication in the supply chain (registration, SDS…), substances screening and prioritization, or also to launch a regulatory action under authorisation, restriction or CLH (harmonised classification). This is useful to avoid unnecessary testing, and address to a certain extent uncertainties related to hazards, risk profiles, uses or releases of similar substances. However, it can create challenges for industry when it comes to the predictability of the measures, and the communication of information along the supply chain.

Cefic explained that the predictability and rationale behind grouping can be difficult to understand for companies and wished to understand if NHDs receive questions on grouping from industry, in particular from Downstream Users, and if so, how those questions are addressed.

Discussion

NHDs explained that when they receive questions on grouping, those are considered on a case-by-case basis as substances identity questions. Such questions have been received a lot recently in relation to the ongoing universal PFAS restriction proposal process. These questions become difficult when a lot of sectors are impacted, and it is noted that NHDs do not always have the knowledge to answer them.

The Chair also noted that it can be difficult for ECHA to address questions on processes that lay with the Member States or ECHA Committees.

NHDs indicated that they do not receive such questions relating to substitution plans.

Closing of the REACH Workshop

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

18th HelpNet Steering Group meeting

The 18th HelpNet Steering Group meeting, organised for the members and observers of HelpNet, took place on 24 May 2023, in Helsinki.

This document summarises the topics discussed[5] during the meeting (Annex I), the follow-up action points (Annex II) and the list of participants (Annex III).

Opening the Steering Group meeting

The Chair, Erwin ANNYS (ECHA, Head of Unit Support and Enforcement) opened the 18th Steering Group meeting and welcomed representatives of national helpdesks, observers from candidate and third countries, observers from industry and invited speaker.

The Chair then introduced Dr Sharon McGuinness who was appointed by the Management Board as Executive Director and took up her role on 1 December 2022. Prior to joining ECHA, Dr McGuinness was the Chief Executive Officer of the Health and Safety Authority in Ireland, and a member of ECHA's Management Board between 2014-2021 and Chair of the Board between 2016-2020.

At the time of the Steering Group meeting, the Executive Director was visiting Austria and Hungary, therefore the speech was recorded.

Opening by the Executive Director of ECHA, Dr Sharon MCGUINNESS

Dr Sharon McGuinness welcomed the participants highlighting how delighted she was to give an opening speech at the HelpNet. Coming from a Member State, Dr McGuinness is familiar with the structure and work of the bodies and networks of the Agency, including the HelpNet, and she is aware of the importance of the work done by representatives of helpdesks at national level. She highlighted that the support given by the network to duty holders, interested players to the development and implementation of BPR, CLP, REACH and all the other chemical areas is of key importance to ensure they implementation of the chemicals legislation within our respective remit.

ECHA is looking forward to onboard new tasks and to implement changes brought to the Agency by the Chemicals Strategy for Sustainability. In that respect, ECHA is looking into new tasks coming to the Agency, such as the Drinking Water Directive, potentially restriction on hazardous substances. Also on these, albeit not all within national helpdesks mandate, Dr McGuinness underlined how there could be cooperation as the network and its connections could help to reach the relevant stakeholders.

The outcome and the impact we can make together for all EU chemical legislations would not be the same without the strong collaboration with the representatives of the HelpNet. Dr McGuinness concluded her speech with thanks for the good work done so far and wishing the network will continue to work together for the protection of human health and

[5] 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.

the environment and continue giving a harmonised support to all relevant stakeholders.

HelpNet 17 - follow-up of action points

The Chair presented the list of action points from the previous Steering Group meeting held in October 2022. Out of the ongoing action points, national helpdesks and ECHA will continue to exchange awareness raising messages through their communication channels.

Approval of the HelpNet 18 draft agenda

The Chair introduced the draft agenda which was adopted without further comments. He requested the HelpNet members to verbally express their concerns[6] (if any) on the attendance of observers or invited speakers at particular agenda points. No objections were raised.

1. Updates from the HelpNet Secretariat

1.1. ECHA preparing for new tasks

The Chair, Erwin ANNYS (ECHA), gave an update on how ECHA is preparing for new tasks, while focusing on its strategic priorities, and to make the best use of staff competences to take on new responsibilities.

Ongoing tasks:

- SCIP, the database for information on substances of concern in articles as such or in complex objects (products) established under the Waste Framework Directive (WFD).
- OELs, occupational exposure limits, the regulatory values which indicate levels of exposure that are considered to be safe (health-based) for a chemical substance in the air of a workplace.

Onboarding tasks:

- Drinking Water Directive (recast). ECHA is preparing the IT tools and organisation work starting with 2024.
- Cross border Health Threats Regulation. This regulation is handled mostly by the European Centre for Disease Prevention and Control (ECDC), but there is a task for ECHA related to potential cross-border disasters in chemical installations.
- Battery Regulation. This task is very close to what ECHA is already doing under REACH restrictions. The task is expected to start next year.

Tasks which are in the legislative process:

- Industrial Emissions Directive
- Water Environmental Quality Standards (EQS) Directive
- Water Framework Directive and Ground Water Directive

Under ongoing discussions with the European Commission are also tasks which are close to what ECHA is already doing. These tasks might include the following: Cosmetics Regulation; End-of-Life Vehicles (ELV) Directive (also very much restriction based work); Persistent Organic Pollutants (POPs) Regulation (waste limit values); Medical Devices Regulation,

particularly reconsidering the phthalates used in medical devices, every five years; Toys Directive and more.

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

In addition, with the purpose to facilitate the 'One substance, one assessment' process, the European Commission plans to review and improve the current way of how chemicals' required data are gathered and disseminated under different EU laws. The Data Platform will integrate among other existing platforms the following:

- Information Platform for Chemical Monitoring (IPCHEM)
- EU repository of health-based limit values, partially coming from EUCLEF
- EU Common Data Platform for Chemicals

Finally, some of the tasks completely on hold are the Sustainable Products Regulation, Tobacco Directive, and F-gas Regulation[7].

The Chair concluded by underlining that ECHA is clearly moving from being a REACH driven agency to a chemicals management agency.

Discussion

One correspondent voiced that the work coming to ECHA is impressive and wanted to know how these changes will impact ECHA staffing and the national helpdesks not having in their remit as many pieces of regulation as ECHA. The Chair responded that this will depend on the decision by the Commission on the number of staf for ECHA.

The Chair noted that the management of ECHA is reflecting on this, mostly on the impact of future enquiries coming from all over the world on all these regulations to ECHA's helpdesk. ECHA is aware that national helpdesks within the network are responsible with the implementation of REACH, CLP, BPR and possibly a few more. Currently, the number of staff ECHA will need and receive is under discussion, as well as what the basic regulation for ECHA will be.

1.2. HelpNet update

Elena BIGI (ECHA), Team Leader of the Regulatory Support Team, gave an update on HelpNet activities, in particular on the cooperation with the national helpdesks, on the new IPA tasks Instrument for Pre-Accession, candidates and pre candidates countries), a peek at future activities (videoconferences, ECHA conference in 2024); updates on our tools (Q&A and S-CIRCABC and new functionalities, the new LIZY tool to encode questions, and the life expectancy of the HelpEx tool). Moreover, an update on the redirection on questions, with a stable percentage as last year of 18-21 % (EU, non-EU) was given. Elena BIGI concluded with and update on sanctions and ECHA's lines to take, an outline of the new process of freezing of dossiers in the form of temporary revocation for listed companies.

Discussion

One national helpdesk asked whether the new LIZY tool would change the way to communicate with ECHA, to which Elena clarified that this concerns questions asked via the ECHA contact form, while HelpEx will remain for the current use by the National Helpdesks until end 2024. After that a new tool might be introduced.

Statistics on the redirection of questions divided by countries were also asked, and Elena confirmed this would be added to the slides (AP1) and to the annual report the Secretariat

[7] EU legislation to control emissions from fluorinated greenhouse gases (F-gases), including hydrofluorocarbons (HFCs). The European Union has adopted two legislative acts: the F-gas Regulation and the MAC Directive.

presents at the end of the year on the redirected questions and division per countries.

A question on the VCN was also raised, and its link to HelpEx and FAQ: An idea could be to bring HelpEx unsolved or HelpEx questions as such, including FAQ, to the VCN: one does not exclude the other. A FAQ draft can be discussed at the VCN; however, the specific process for those including written procedure according to the Handbook would still apply. Another national helpdesk expressed the wish to have the VCN questions connected somehow to the HelpEx tool.

Moreover, a national helpdesk outlined the need to have all national languages in the restrictions table that is on the ECHA website. The HelpNet Secretariat will take this up with restrictions colleagues (AP2).

Action points

AP 1: Annual report on questions redirected to NHDs will be provided by the end of the year with details on countries redirection. Slides with the countries' details will be also added to the current presentation.

AP 2: Consider the possibility to link the restrictions' texts in national languages on the 'Substances restricted under REACH' webpage of ECHA[8].

1.3 Report on annual activities

Amandine JOMIER (ECHA) thanked the NHDs for their input to the annual survey and provided a brief overview of the published report on national helpdesks and ECHA's activities in 2022[9], highlighting the figures and hot topics of regulatory enquiries received in the past year. Amandine JOMIER also presented how the structure of the report had been updated to emphasise the increased cooperation between the NHDs and ECHA. This new structure and other considerations opened the discussion on reviewing the annual survey.

Evelyne FRAUMAN (ECHA) introduced the HelpNet Secretariat's reflection on how to adjust the survey and highlighted the need to ensure meaningful and representative data is used to prepare the report on annual activities. For this, it was proposed to clarify questions for which the HelpNet Secretariat had identified diverging interpretations by NHDs when providing their responses, and to use existing synergies between NHDs data collection for own purposes and ECHA's report data collection. The purpose of this presentation was also to agree on the objectives of the report, ensuring a common understanding across NHDs, and understand how the report may be used by them.

The NHD representatives were invited to share their views and feedback on the report in the discussion or later via email to the HelpNet functional mailbox.

Discussion

One NHD thanked the HelpNet Secretariat for the report, which they found useful and a good reflection of all the work accomplished by the different helpdesks. The correspondent underlined the need to ensure that the data collected is indeed understood in the same manner by all NHDs responding to the survey and how this is important to ensure that the report includes meaningful and comparable information. The NHD also enquired whether and how national helpdesks may be asked to provide more data in relation to the new tasks, and whether an increase in activity is expected.

[8] https://echa.europa.eu/substances-restricted-under-reach
[9] Link to the public version of the report: 2b0f75be-4272-032c-c06c-4aceb8382dbf (europa.eu)

The Chair acknowledged the need for clarity in relation to the new tasks and the support to be given to duty holders, in particular to SMEs. The Chair mentioned the internal discussions currently taking place on how ECHA will support companies in relation to the news tasks. He also highlighted the huge number of questions that is expected to come in relation to the notification/registration of polymers. At present, ECHA is starting to look at the guidance needed in the context of the CLP revision.

Action point

AP 3: ECHA will consider how to harmonise the collection of data from NHDs in the annual survey and report.

1.4 Borderline Working Group - Aggregates assessment

ECHA introduced the Ideas Jam items: every participant has been allocated a colour visible on their name holder. The next speaker introduces the topic. Participants then move to the Marie Curie room next door where they find their respective 'coloured' table. At each table, participants discuss the questions introduced by the speaker and after 15 minutes, all participants come back to this meeting room. The groups are invited to report on their discussions.

This introduction was followed by a presentation by Telmo VIEIRA PRAZERES (ECHA) about the proposal from the Borderline Working Group (BWG) to revise the assessment of recovered aggregates following the discussions that took place in the BWG during the first half of 2023 – in February and April.

Telmo VIEIRA PRAZERES presented the agreed revised assessment by the BWG, which concluded that recovered aggregates cannot be regarded as articles under REACH as currently specified in the 'Guidance on waste and recovered substances' but are instead substances or mixtures. Indeed, these recycled aggregates are not given a special shape, surface or design during production (usually by crushing), and no special physical form is required for the aggregate particle to perform its main function, be it as ingredient to formulate mixtures in bound applications, or as filler in unbound applications.

Standards and regulations exist for recovered aggregates. These are based on particle density, size and size distribution, and composition of the aggregates. The presenter noted that the concept of shape, size and surface applicable to these standards should not be confused with the definition of shape and surface under the REACH regulation.

The BWG proposed to gather support from the HelpNet members and request a review of the recovered aggregates assessment in the ECHA 'Guidance on waste and recovered substances'.

Discussion

Participants divided in groups of seven members to discuss the following topics:

- Do NHDs agree with the proposed approach? What are the remaining concerns?
- How is this topic addressed in the EU countries?

Do NHDs agree with requesting an update of the 'Guidance on waste and recovered substances'?

One group was in clear opposition with the BWG conclusion. In general, participants noted that whilst they agreed with the conclusions reached by the BWG, they discussed mostly the

consequences of those conclusions.

One NHD noted that the consequence of reaching the conclusion that recovered aggregates are substances/mixtures is that the substances would have to be registered. The correspondent mentioned that registering those substances would not have anything to do with fulfilling the main purpose of REACH of protecting human health and the environment. Instead, it would mean requesting additional data that would be too burdensome for the purpose sought. Another NHD highlighted the difficulty for recycling operators to know what substances are contained in the mixtures, how to classify them, etc. Exemption for substances already registered and recovered through a recovery process in the EU should be demonstrated.

However, there was a general understanding that the BWG's mandate consists of reaching agreements on the assessment of borderline cases of articles and substances/mixtures. The scope of the work of the HelpNet on this specific topic is to determine whether recovered aggregates are mixtures or articles. The consequences of these conclusions are not in the scope of work of this working group. Additionally, one NHD noted that the identification of objects as articles or substances/mixtures should not depend on the consequences of such identification.

Finally, the existence of a study on circularity of construction products in Finland was noted, where additional information may be found to help in this discussion.

Action points

AP 4: Launch a written procedure on the conclusion of the BWG for recovered aggregates and the need to review the guidance on waste and recovered substances.

2. Updates on ECHA activities

2.1 Update from IT External Support team

Peter SIMCIC (ECHA), team leader of the IT external helpdesk (iTEX), outlined the services provided by iTEX to industry, authorities, and other stakeholders on ECHA's IT tools (IUCLID, Chesar, REACH-IT, R4BP, ECHA submission portal, Interact Portal) and information disseminated on the ECHA website.

iTEX is the first point of contact for external users encountering issues with ECHA's IT tools. In 2022, the helpdesk replied to 5 092 technical enquiries, of which 1 722 on REACH, 923 on PCN, 882 on IUCLID/Chesar, 765 on WFD, 632 on BPR and 168 on CLP.

While for the Regulatory Support Team (REST) the number of enquiries may decrease while complexity increases, for iTEX ECHA observes a regular spike in the number of questions following an IT tool release. In 2022, ECHA had around 50 IT tool upgrades which frequently triggered an increase in technical questions.

Peter SIMCIC talked about installation, upgrades and functionalities of IUCLID, dossier creation, submission of dossiers to ECHA via submission IT tools, the support material prepared by the team, including publishing technical questions on ECHA website[10].

He then referred to ECHA's new tasks, some of which may be linked to the submission of data to ECHA. In order to rationalise the submission portfolio and harmonise the user experience, a new submission strategy will be addressed in the webinar Future of ECHA's submission systems[11] on 6 June.

[10] https://echa.europa.eu/support/qas
[11] https://echa.europa.eu/en/-/the-future-of-echa-s-submission-systems

An important role of the team is to provide support on dissemination, monitor the correctness of the information displayed and provide instructions on search functionalities and data

extraction. He stressed that the dissemination pages have outgrown their initial design and reached the end-of-life stage. More information will be presented under the agenda item 2.4 Update on dissemination activities.

He then presented the role of iTEX in product support, starting with gathering feedback and ideas from industry and user groups, participating in testing of new IT releases and reporting back to the product teams.

Peter SIMCIC ended his presentation with a request addressed to national helpdesks on a project initiated in the unit.
REST and iTEX would like to create support cards on the support page that provide an information package on activities and campaigns triggering questions to ECHA helpdesks and national helpdesks, e.g. the new hazard classes.

Feedback and ideas are very much welcomed (help-net@echa.europa.eu).

2.2 Communication activities

David CLIFFE (ECHA) is the new Head of Unit of Communications. Before joining ECHA in 2022 he worked in the European Securities and Markets Authority (ESMA) in Paris, the International Organisation of Securities Commissions (IOSCO) in Madrid, and the Financial Services Authority (FSA) in London. His background is financial regulatory communications.

David CLIFFE gave a presentation on ECHA's communication activities, including the stakeholder engagement review launched in 2022, and ECHA's new communication strategy in support of ECHA's strategy from 2024 to 2028. In this regard, NHDs were reminded about the Communicators' Network and the following meeting scheduled for September this year.

He then introduced the new approach methodologies to support alternatives to animal testing and the discussion with stakeholders during the workshop scheduled from 31 May to 1 June. The event will be web streamed, and 300 participants are expected in Helsinki from all stakeholder groups.

On the Chemicals Strategy, the revision of CLP and REACH will bring new tasks for ECHA, new stakeholders and new areas to communicate about.

David CLIFFE mentioned the most popular themes for ECHA: grouping of chemicals, bisphenols, SCIP database, RAC and SEAC meeting outcomes. Also, the restriction proposal of per- and polyfluoroalkyl substances (PFAS) - the 'hot substance of the year' – with a high media and stakeholder interest for which a call for evidence started in March, running until September.

Various channels of communication used to raise awareness were mentioned: the ECHA website, newsletters, direct contact with media, safer chemicals podcast[12], joint Instagram account - One Health One Environment EU – with the European Food Safety Authority (EFSA), European Environment Agency (EEA), European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).

[12] https://echa.europa.eu/podcasts

2.3 Forum activities

Maciej BARANSKI (ECHA), team leader of the Harmonised Enforcement Team, gave an overview of the work done by the Forum from Q4 2022 to Q2 2023, particularly giving a brief update on the following projects:

- REF-10 – Integrated project on products (2021-2023) for which data was collected by 30 March, currently being under analysis. The report on the project will be available and published at the end of 2023.
- New Pilot project on control of substances restricted under POP and REACH focusing mainly on cosmetics was launched in March 2023. A manual is under preparation, controls should start at the end of 2023 and a report will be available at the end of 2024.
- REF-12 – Control of imports (2022-2024). The core scope is the REACH Registration, Authorisation and Restrictions for imported substances, mixtures and articles in cooperation with customs. A manual is in preparation and controls will start in 2024.
- REF-11 - Project on Safety Data Sheets (2022-2024). Inspections take place in 2023, and results will be available in 2024. A 'Training for trainers' – attended by 55 participants on site and nearly 200 joining online – took place in 2022 focusing on SDS control and the new Annex II.
- REF-9 – Project on authorisation (2020-2022). The Report was published in March 2023 and a Workshop with industry and stakeholders took place in May 2023. The Practical guide for inspectors is under preparation.

Regarding other REACH enforcement priorities:

- Registration - Pilot project on recovered substances is finished. The project Report was published in November 2022 and shortly after, the Forum held a Workshop with industry and stakeholders to discuss the results.
- Authorisation. The Report was published in March 2023 and a Workshop with Industry and Stakeholders took place in May 2023. The Practical guide for inspectors is in preparation.
- Restrictions. The Forum delivered advice on enforceability of new restriction proposals (e.g. Terphenyl, DMAC, Creosote). It also decided to make its enforceability advice public starting from new advice prepared in 2023. Delivery of enforceability advice on the upcoming Commission proposal for CMRs in childcare articles was under consideration.

CLP enforcement priorities:

- Pilot project on classification of mixtures (2022-2023). The project aims to structure the approach for using bridging principles, weight of evidence and expert judgement. The Guide for inspectors is under preparation covering the control of classification of mixtures, proposing a clear approach for enforcing cases where companies use bridging principles, weight of evidence or expert judgement.

BPR enforcement priorities:

- BEF-2: Biocidal products and active substances (2021-2023). Inspections finished last year, a report is under preparation and will be published in Q4 2023.

- A training for BPR trainers on classification and labelling of biocidal products took place in December 2022, attended by 430 remote participants.

Maciej BARANSKI highlighted the recent opportunity for the Forum to contribute to the

Commission work on the implementation of the Chemicals Strategy for Sustainability. In December 2022, on Commission's request, the Forum gave feedback on the potential mechanisms for improved control of imports of substances, mixtures and articles.

Discussion

Two correspondents noted the increased number of TARIC codes[13] related enquiries received by their NHDs and the need to coordinate within HelpNet or at the Forum level.

Action point

AP 5: ECHA will inform the HelpNet on the result of Forum discussion on the practical implementation of the new TARIC codes for REACH restrictions when it is finalised

2.4 Update on dissemination activities

Eoin BRENNAN (ECHA), Product manager of the current dissemination platform, gave an overview of the upcoming changes in ECHA's data dissemination activities.

The current ECHA Dissemination Platform has reached the end of its life. Since January 2022, ECHA has already begun work on a replacement, using modern technology and being legislation independent – the new Data Availability System (DAS).

The presentation of Eoin BRENNAN gave some background details and a sneak peek at what is to come, an overview of the timelines and foreseen transition. All data now published in the current Dissemination Platform will be gradually migrated to DAS, starting in November 2023 with REACH registration dossiers.

By the end of 2024 the C&L Inventory and key regulatory lists will follow. During the transition period it was clarified that data may be published in two places – up to the stop date in the current Dissemination Platform, integrated to the ECHA website, and a complete up to date set in the new DAS.

The transition to DAS is a multiyear project with many benefits and improvements. Cross links and guidance will be provided, including webinars on the new system. The first webinar 'New ECHA public data availability system' is already available on ECHA website[14], and the Q&A gives helpful insights into what will happen.

Discussion

Representatives of NHDs wished to know if in the C&L inventory an advanced search functionality will be available and if it will be possible to export XML data and link it to a company; when BPR information will be published in DAS and if there will be Infocards.

Eoin BRENNAN replied that there will be an advanced search in the new C&L inventory in DAS.

DAS will be designed with many data export possibilities, and it is planned to have as at present downloads in XLS and perhaps other formats, but potentially system-to-system connections through the Application Programming Interface.

[13] Integrated Tariff of the European Communities
[14] https://echa.europa.eu/-/new-echa-public-data-availability-system-part-1

BPR data will be integrated to DAS but there is no definite date as yet. The first datasets to be integrated will be, in order, REACH registrations, C&L Inventory, and key regulatory lists.

There will be an equivalent to Infocards in DAS, a so-called substance dashboard page. The current Infocards will remain online in the current system in parallel. To be kept in mind that the new DAS substance dashboard and the related current Infocard will each have partial

information, during the transition period.

Validation of information – ECHA has neither the mandate nor the resources to validate submitted data under the CLP Regulation. That said, Eoin BRENNAN clarified that ECHA is designing some automated screening functionalities which might allow the highlighting of outlier or clearly suspect information. It is not possible to automatically validate the information submitted. With regard to validation of REACH registration data, in accordance with REACH a proportion of the registrations are picked up for compliance checking under the evaluation processes.

Finally, Eoin BRENNAN clarified that new C&L Inventory each substance's data will be compiled into a single page, which will contain the harmonised classification(s), and distinct self-classification(s) submitted, along with indications of the proportion of notifiers agreeing with each self-classification.

3. Update from candidate countries

3.1 An introduction to the work of the Serbian helpdesk

Jelena GRUJIĆ (Serbian helpdesk) gave a presentation on the Serbian helpdesk activities[15]. The presentation was jointly prepared with Snežana JOKSIMOVIĆ and Bojana ĐORĐEVIĆ.

The Serbian helpdesk, established in 2009, is currently located within the Ministry of Environmental Protection. The helpdesk is answering questions on the application of the Law on Chemicals, the Law on Biocidal Products, assisting duty holders placing chemicals and biocidal products on the Serbian and EU market.

Also, the helpdesk is actively involved in raising awareness on the European standards for the chemical industry, updating the information on the official website of the Ministry, publishing guidelines, brochures, frequently asked questions and participating in seminars, workshops, conferences, as for example the Serbian Stakeholders' Day held between 2019 and 2022. In addition, several events were organised in cooperation with the competent authority in Sweden (Kemi) and the Chamber of Commerce and Industry of Serbia (CCIS).

As a part of the National Strategy for the Environment, special attention will be dedicated to the education of business entities, supporting the reduction of hazardous chemicals in production processes, optimising energy efficiency, the minimization of waste, wastewater and emissions into the living and working environment.

Regarding human resources, two employees are engaged in helpdesk activities, working in various divisions of the authority (e.g., REACH, CLP, BPR, PIC and POPs). Depending on the complexity of the question, helpdesk employees answer questions from industry independently or by consulting other colleagues in the Department of Chemicals.

Jelena GRUJIĆ ended her presentation by referring to the action plan and the study on the readiness of Serbia to implement the EU acquis on chemicals (REACH, CLP, BPR, PIC) performed under the IPA project: Assessment of the national capacity and readiness to implement and enforce REACH, CLP, BPR and PIC in Montenegro and Serbia (WP5).

[15] Information desk for chemicals and biocidal products available at:

Discussion

It was clarified that in Serbia, the Rulebook on bans and restrictions is harmonised with Annex XVII of REACH Regulation, as well as with Annex I of POPs regulation.

Regarding enquiries received from customers by phone or email it was explained that basic questions received by phone are answered on the spot while more complex ones or those

requiring additional information are replied in writing (by e-mail).

4. Training session

4.1 HelpEx training

Discussion

The training addressed some of the HelpEx functionalities, particularly how to:

- Search for (similar) HelpEx questions
- Create and finalise a new HelpEx question
- Modify a HelpEx question
- Close a HelpEx question
- Set a question to unsolved
- Re-open a timed out question
- Search and report on HelpEx questions

The HelpEx Quick Guide and the reports on timed-out and unsolved questions are available in S-CIRCABC[16] for HelpNet members and observers.

Closing of the HelpNet Steering Group meeting

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

[16] Path:/CircaBC/echa/HelpNet/Library/03 HelpEx. Browse url: https://webgate.ec.europa.eu/s-circabc/w/browse/3338b925-5984-4133-87f5-6b5c14fa0535

CLP Workshop

Opening by the Chair

The Chair, Erwin ANNYS (ECHA) opened the CLP Workshop by welcoming the representatives of the European Commission, national helpdesks (NHDs) and observers.

The Chair presented the draft agenda of the day, which was approved without comments. Afterwards, he reported on the list of action points from the CLP Workshop in October 2022, out of which only one remained pending.

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

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission

Svetlana SKRYNIKOVA (European Commission, DG GROW), representing the CLP team, first gave an update on the CLP revision. Both texts (the delegated act and the proposal for the ordinary legislative procedure, OLP) were published on 16 December 2022. The OLP had already started, with parallel discussions in the Council (EC) and in the Parliament (EP). Based on the ongoing discussion, COM considered it possible that the EC would reach their agreed text at the end of June. They would therefore be able to start negotiations with the Parliament in the autumn, under the presidency of Spain. The EP Committee on the Environment, Public Health and Food Safety has already planned a vote in September. The expected timeline would continue with an announcement in the plenary in October, after which the trialogue step could start. If the positive attitude from the three parties (COM, EC and EP) would continue, it would be feasible to have a political agreement by the end of the year. It would then be under the Belgian presidency, starting 1 January 2024, that the file would be finalized. The hope remained of having the new text published in summer 2024.

Svetlana SKRYNIKOVA then explained some specific parts of the revision. Regarding the poison centre notification (PCN) obligations, the targeted revision aimed to clarify provisions and close legal gaps. One of the provisions clarified was ECHA's role in Article 45, by explicitly adding the possibility for ECHA to be the body appointed to receive information, which had been missing in the legal text before. Article 50 will mention that in this case ECHA will be responsible for providing the necessary IT infrastructure. The main legal gap closed was that of distributors who re-label or re-brand the mixtures or place them on a different Member State to that of the first notification. The revision would list them as duty holders, therefore avoiding the risk of poison centres missing information.

In this context, the COM representative informed that they had asked the Member States Competent Authorities (MSCA) to update the contact details of their appointed bodies. They got only four replies, so they would send a reminder. COM was also closely following the connection to the ECHA systems of the last Member States to do so. One of them informed on that day that they were ready to connect.

The delegated act, now Commission delegated regulation 2023/707, entered into force on 20 April, as there had been no objections from the European Council nor the European Parliament.

The next topic was the ATPs (Adaptation to Technical progress), starting with the 18th one with application date 1 December 2023. The next two ATPs were adopted but not yet published:

19th and 20th. Those ATPs introduced the notes to Part 1 of Annex VI, assigning them to the relevant harmonised entries. These notes would provide legal clarity and certainty on how to apply the harmonised entries to two specific substances.

The delegated acts following RAC opinions on harmonised classifications from 2021 were delayed because of the CLP revision but were still expected to be adopted before the summer and published in Q3. The opinions from RAC in 2022 had been discussed already in March in CARACAL and COM had hopes to still adopt them this year.

COM and France had separately appealed against the general court ruling on the harmonised classification of Titanium dioxide (TiO2). Svetlana SKRYNIKOVA clarified that as the judgment has been appealed, companies have to comply with the harmonised Classification and labelling of titanium dioxide (TiO2) until the higher Court (European Court of Justice, ECJ) provides a new ruling or dismisses the appeals Other ongoing court cases were the two most recent related to silanamine and N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA) and its pentasodium and pentapotassium salts, and an older one related to Dioctyltin dilaurate (DOTL), whose outcome was expected in July this year.

And finally, the list of tobacco-like products that the HelpNet had sent to COM was the matter of discussions with DG SANTE. This topic would also be added to the agenda of the CARACAL meeting in July for information and follow-up discussion.

Discussion

There were no questions raised to the COM representative.

1.2 How ECHA is preparing for the delegated regulation: guidance, IT tools, support material

Konstantinos PREVEDOUROS (ECHA, Hazard Unit) introduced himself before briefly recapping on the Delegated Commission Regulation 2023/707. This included presenting the new hazard classes with codes and statements. He clarified that there could be no new pictograms to avoid a negative impact on international commerce, as these hazard classes are absent in the UN GHS.

The next point was about the update of the Guidance on the application of the CLP criteria. Since some of the hazard classes are part of the Biocidal Products Regulation, this update was being done in cooperation with the Biocidal Products Units in ECHA and the European Food Safety Authority (EFSA). The Partner Expert Group (PEG) meeting on Persistent, Bioaccumulative and Toxic (PBT) properties had already taken place the previous week, and the one on Endocrine Disruptors (ED) would take place soon. There were both *ad hoc* consultations, prior to the formal request to MSCA and Accredited Stakeholder Associations (ASO) to nominate experts. The plan is to have four ongoing parallel consultations.

Konstantinos PREVEDOUROS ended his presentation by explaining the idea embedded in the ordinary legislative process of CLP, to move to a centralised procedure to establish the harmonised classification and labelling of substances. The hazard assessment for several pieces of legislation would be done in one single Committee, rather than by different sectorial bodies. These were the foundation for the One Substance One Assessment (1S1A) principle. Additionally, COM was considering a fast-track procedure to move the already identified hazards of substances via the Candidate List into harmonised classification and labelling entries.

Discussion

During the discussion it became apparent that the application dates were not fully clear from the legal text but were mentioned in the Annexes. A correspondent asked if it is already now possible for industry to notify and hence to find the new hazards classes in the public C&L

inventory. The Chair took note to reply to this question after internal consultation.

Another correspondent asked about the organisation of the PEG for ED, as this hazard has two sides (for human health and for environment) which may require different expertise and therefore different experts from the MS. The ECHA representative replied that this was under consideration: on the one hand those different experts could even be outside the MSCA for CLP, and on the other hand, handling two PEG instead of one required an administrative overhead which could affect its performance. This, however, should be clarified in the following weeks, when ECHA would send the letters for the nomination of the experts.

It was also asked if the templates for proposals for CLH had been updated, and if there was already a mandate for MS to submit proposals for active substances under BPR. The ECHA representative replied that the standard template had been updated and was published. However, the combined template for BPR-Competent Authority Report (CAR)-CLH was still under revision. The PPP template is on COM's mandate, but ECHA was supporting them to update it.

ECHA took the chance to clarify that these new hazard classes have an impact on the product identifiers for mixtures (Article 18(3) of CLP) and had already contacted COM and the Swedish presidency to consider the relevant amendment of the legal text.

Konstantinos PREVEDOUROS closed the discussion and announced that COM had the intention to review the downstream legislation affected by the new hazard classes.

Action points

The HelpNet Secretariat will consult internally on whether the ED and PBT properties can be shown already in the C&L inventory.

2. Topics proposed by HelpNet members and observers

2.1 How can national helpdesks support companies with information on new harmonised hazard classifications

Jonas FALCK (Swedish helpdesk) introduced his topic by explaining that this concern was about the CLH process in general, beyond the introduction of the new hazard classes. The main question was if, and when, affected companies would become aware that the substance of their interest was being proposed for CLH, and also the impact on downstream legislation. This means not only that companies in practice need to review the classification of the mixtures in which the substance is included, or updating the labels and safety data sheets, but also need to sell their stocks on time. Some new classifications trigger restrictions or limitations, and companies will not be able to sell their products any longer. This places an extra stress on them. Jonas FALCK also highlighted a practical issue, when the new CLH targets a group of substances: it becomes challenging to identify them, or to realise that the substance of interest is included. He concluded his presentation with the open questions: should NHD just publish or promote the information of the registry of intentions, or similar lists? Or should NHD be more proactive in targeting the impacted companies?

Discussion

One correspondent mentioned that they only inform about published ATP, and that they themselves have challenges in following the discussions about CLH.

One ECHA representative informed that registrants and notifiers of the substance under consideration are informed by REACH-IT. This information was welcomed by the

correspondents[17]. Another correspondent shared their thoughts that maybe 27 national helpdesks working on an *ad hoc* basis was not the way forward, and a more holistic approach should be considered, at EU level.

The Chair mentioned the case of a non-exhaustive list of salts in a harmonised entry (benzidine) where the description went beyond the actual substance and its salts. This was noticed by the inspectors trying to enforce it. It was acknowledged that group entries were always difficult and complicated to handle. The Chair asked the participants to raise these issues to ECHA if they identify new ones.

Jonas FALCK mentioned that the Swedish NHD also provides links to the ATP, with a note highlighting what they think is important. Public consultations are also promoted through their website, though the question remains: what about the companies which do not check their website? Probably a more holistic, EU approach would be more effective.

2.2 How the German national helpdesk is preparing for the CLP revision

Anja HACKMANN (German helpdesk) outlined the work done by the German NHD around the new hazard classes. They had identified the need for Industry to have dedicated support and had already provided it. This included a specific logo, a dedicated webpage, a webinar, and a brief support document called "Helpdesk compact".

Discussion

One correspondent thanked the German helpdesk for presenting their work, finding it inspiring. For them, it was a matter of knowing when to do what.

Anja HACKMANN commented that FAQs were a useful means to provide advice to companies, which they appreciated. Additionally, to their surprise, this webinar had more participants than the previous one they organised about the proposal for the PFAS restriction.

In this context, the Chair informed the attendees about the CLP Information Session organised by the HelpNet Secretariat to the Instrument for Pre-Accession (IPA) beneficiaries. The presentation could be used as information material by the different NHD.

Action point

The HelpNet Secretariat will circulate the slides of the CLP Information Session to IPA beneficiaries.

3. Poison centre notification. Break out session

3.1 Annex VIII application date for industrial uses: communication campaign and support

Pedro ROSELLÓ VILARROIG (ECHA) reminded the participants about the second compliance date, for industrial use type mixtures, along with certain requirements and derogations. There was also a brief presentation of the draft communication plan, and a reminder about the Communicators' Network.

Discussion

A CLP correspondent asked if they could already promote the date of 14 November for the webinar. The HelpNet Secretariat committed to come back later, also when the different items

[17] Post meeting clarification. A message is sent from ECHA to all notifiers and registrants of the substance through REACH-IT. This is done after the accordance check and before the public consultation.

of the communication plan would become definitive. The Chair already told the correspondents that ECHA would then ask them to promote this material, to increase the reach of the message.

The same correspondent pointed out that they had already received the invitation and acknowledged the overlap of the Communicators' Network and the HelpNet. They considered that they were not the appropriate people to join that network. ECHA clarified that the message was to identify the communicators expert, or experts, in the institution where the NHD would be part of, to whom to pass on this message. Indeed, it is a specific expertise which is not expected to be in the NHD.

Another CLP correspondent asked to confirm the wording of the UFI derogation in SDS. ECHA confirmed the wording: "If the mixture is supplied at an industrial site, the UFI **can** be in Section 1.1 of the SDS. In this case, the inclusion of the UFI in the label or package is not mandatory".

Action point

The HelpNet Secretariat will keep NHD up to date about the communication campaign for PCN compliance date.

NHD will promote the webinar in November once the information is published.

3.2 e-liquids: notification duties, advertisement, labelling and enforcement

Maria PALEOMILITOU (Cypriot helpdesk) introduced several issues with e-cigarettes and e-liquids that concern the Cypriot NHD. They have been discussed several times, but many uncertainties remain. Tobacco, tobacco-like and non-tobacco products have become popular in recent years, with overlaps and gaps with CLP, mainly. Innovations from Industry make it difficult for NHD and also inspectors to understand which legislation applies. Late last year the HelpNet Secretariat sent a document to the attention of COM with a number of cases, for their consideration. The presentation finished with several questions to gather the opinion and experiences of the other CLP correspondents on these matters.

Discussion

One correspondent thanked Maria PALEOMILITOU for raising the issue. They noted that while some NHD had not received any question at all about tobacco nor tobacco-like products, others do receive them in large amounts. The problem of having double regulation with double labelling and notification obligations was immediately identified. They hoped that this matter would be tackled by the COM in the ongoing CLP revision.

A correspondent pointed out that CLP is not fit for consumers. However, other legislations fail to properly cover new products and CLP ends up applying. He also added that non-nicotine pouches are a big problem in their country, and this legal uncertainty was not helping to solve it.

Another correspondent explained that single use cartridges for e-cigarettes could be considered as articles, but refills would then be considered mixtures. ECHA replied that a very similar matter (lighters) was being discussed in the Borderline Working Group. In it, REACH correspondents and ECHA experts discuss practical cases of objects, which can be considered as articles, or not.

A correspondent mentioned that their NHD could only provide advice from the CLP point of view and insist on compliance. However, the lack of competence and therefore knowledge of other legislations made it difficult to provide useful advice to industry. They suggested a pilot project with the Forum to publish Q&A specifically targeting this kind of products.

An ECHA member pointed to the matter of the tobacco-like products list that the HelpNet Secretariat forwarded to COM last year. There were concerning news about some of these products (cannabidiol) causing intoxications and severe damage to people. In her opinion, the TPD could be fitter to handle them rather than the CLP.

A correspondent informed that they regularly get questions about labelling, and the latest trend were HBN products (heated but not burnt tobacco). Additionally, the Medicines authority in their country had decided to consider outside their scope a new product for vaping vitamins, without specifying which other legislation should apply. By default, this should be CLP, which is not suitable for HBN nor similar products. In this context, they pointed to the knowledge tobacco companies have on TPD, and its labelling requirements, but not in CLP labelling and other duties.

Action point

The German CLP correspondents agreed to post in HelpEx their Q&A on tobacco products.

The Chair invited the correspondents to propose to Forum a project on tobacco-like products, through their representative in that committee. He committed to inform his peers in the Forum about this upcoming proposal.

Closing of the CLP Workshop

The Chair listed the action points of the workshop. He thanked the presenters for their contributions and all participants for the interesting discussions. He invited the participants to reply to the satisfaction survey, which would be sent after the meeting. The input provided helps the Secretariat to provide a better service and built an interesting and useful agenda for the following event.

The date of the next CLP Workshop will be 22 or 23 of November in a remote setting. It will be communicated to the CLP correspondents on due time. In the meantime, the Chair reminded the participants about the videoconferences, where discussions can continue.

4. Training session

4.1 Live demonstration on the ECHA submission portal for PCN

Pedro ROSELLÓ VILARROIG (ECHA) went through a simple submission in the trial environment. The CLP correspondents were encouraged to try out by themselves the submission in this safe environment. They were also presented with some practical tips on the management of the ECHA Cloud accounts[18].

[18] After the meeting, the HelpNet Secretariat circulated a take-home messages document based on this live demonstration.

BPR Workshop

Opening by the Chair

The Chair **Elena BIGI** (ECHA) opened the BPR Workshop by welcoming the representative of the European Commission (DG SANTE[19]), national helpdesks (NHDs) and observers.

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

1. Updates from the European Commission and ECHA

1.1 Updates from the European Commission

Ligia NEGULICI (European Commission, DG SANTE) gave an update on biocides' hot topics covering both active substances and biocidal products, as well as scope issues.

COM highlighted that, since only 45% of the substances in the Review Programme have been evaluated, it is clear that the 2024 deadline will not be met and that an extension of the Review Programme is needed. In this regard, it is expected that the Commission will present a Delegated Regulation amending the BPR with respect to the duration of the Review Programme. In addition, COM presented updates on substances that are subject to early review and/or renewal (e.g. propiconazole, iodine/PVP iodine and anticoagulant rodenticides) and the respective consequences for product authorisation. On the topic of skin sensitisers in-can preservative (isothiazolinones), it was mentioned that either the concentration of the substance in a mixture should be lowered so that the mixture is not classified as skin sensitiser cat. 1A (e.g. in detergents), or where lowering the concentration leads to problems in terms of preservation, personal protective equipment needs to be provided (e.g. gloves, in the case of paints).

Regarding biocidal products, a number of different topics were discussed. A recent discussion at the Competent Authorities meeting, concerning trade names and compliance with the provisions of Art 69(2) of the BPR and Art 24(4) of CLP. Member States have agreed that terms such as 'bio', 'green', 'natural', 'organic', etc. are not allowed to be used. Another topic concerned finding and evaluating Competent Authority (eCA) for Union authorisation applications. Applicants have brought to the attention of COM their difficulties in finding an eCA for their applications. It was clarified that while COM cannot oblige MS to accept the eCA role, some initiatives were taken, including offering Member States the possibility to apply for financial support for hiring experts to increase the resource capacity. The speaker also informed about the linguistic review procedure, which has been set in place to guarantee quality translations of the summary of the biocidal product characteristics (SPCs) for union authorisation applications. She then informed of an agreement of Member States to include warning statements in the SPC of products containing pyrethroids, given that exposure to pyrethroids may cause fatal effects on cats. In

[19] Directorate-General for Health and Food Safety

the future, COM intends to issue a joint mandate for ECHA and European Medicines Agency to clarify the risk posed to cats by products containing pyrethroids.

Finally, COM presented a scope issue concerning products with mode of action at molecular level. It was discussed that at molecular level a mode of action cannot be identified as purely physical or mechanical and the distinction between purely physical and chemical mode of action is only possible at macromolecular level. If a product triggers changes at a molecular level, such interactions are actually biochemical, hence the product would qualify as a biocidal product and fall under the scope of the BPR.

Discussion

The Chair asked whether ECHA's active substance action plan has contributed to speeding up the evaluations in the Review Programme, and if yes, to what extent it has had an impact. COM clarified that the action plan was a good initiative from ECHA and has helped to push certain assessments forward, however, in terms of numbers, the delay is still significant and the progress made was not sufficient to resolve the problem.

An observer and an NHD highlighted situations where the term "bio" or "green" is part of the name of the company and asked about how trade names would be handled in these cases. COM noted that a certain degree of flexibility could be applied in such cases, however, the discussions on this topic are still ongoing. This being said, COM emphasised that, at present, the agreed approach is not to accept possible justifications from companies and not to allow those terms in the trade names.

An NHD asked for clarification about heat and radiation, particularly, whether such treatments would fall under the scope of the BPR, or not. COM explained that in principle, they wouldn't fall under the BPR scope, however, in situations where heat and radiation are used to generate an active substance in situ, then the in situ generation system would be covered by the BPR. Another NHD enquired about the mode action, particularly in relation to cationic polymeric binders with quaternary ammonium compounds. COM explained that if a product produces a biochemical effect, this would not correspond to a purely physical/mechanical mode of action, hence it would fall under the BPR. She also advised to have a look at the COM's decision on the polymeric binders for further details.

1.2 Legal update

Valeria D'AGOSTINI (ECHA, LAU) summarised the judgment of the General Court in cases T-122/20 and T-123/20 related to the approval of silver zeolite and silver copper zeolite in treated articles. The speaker highlighted the fact that for the approval of the active substance for use in treated articles, the efficacy of a treated article against harmful organisms does not need to be proven, provided that the efficacy of at least one representative biocidal product in realistic use conditions is confirmed by providing a tier 2 efficacy test. This means that the efficacy test does not have to be conducted with the treated article in the final form as it is placed on the market, but it may be performed with the representative material to be used for the production of the treated article.

She then discussed the shelf-life setting during the authorisation of biocidal products. The speaker informed that the Coordination Group (CG) -53 meeting concluded that if the long-term

storage stability test, which is part of the core data set, is missing, a simple statement that this test is not available is considered a data gap and the dossier is considered incomplete. To pass the validation step, the applicant needs to include in the dossier more information e.g. explain why the test report is not available, provide the written confirmation from the laboratory that the test is ongoing and envisaged timelines for its finalisation, and include at least the measurements at the beginning of the test. If the long-term storage test is still missing during the evaluation phase, the eCA may suspend the evaluation and request additional information within a specified time limit. In any case, the data needs to be submitted before a draft Product Assessment Report is sent for comments. If a longer shelf-life is requested by the applicant a change request (including the supporting data) will need to be submitted after the authorisation of the product.

Lastly, the speaker discussed post-authorisation conditions for national and simplified product authorisations. She highlighted that such conditions should apply as an exception, as they are not regulated by the BPR and can only be set if the data to be provided post-authorisation does not affect the classification and labelling of the product, it does not affect the efficacy, or risk assessment, and it is linked to a timeline. According to the CG document, the eCA is responsible for following up this condition. If the data provided is sufficient, the authorisation conditions will be amended at the product authorisation renewal stage. In any other case, the eCA cancels or amends the authorisation as per Article 48(1)(c) of the BPR.

As both CG documents apply to national authorisations, a similar document related to Union Authorisations is being prepared by the Biocidal Product Committee (BPC) secretariat. The first discussions are foreseen already in June but the final adoption by the BPC is not known yet. The speaker also highlighted that all three documents (both CG documents and the upcoming BPC agreement) will apply only after all of them are published and they will be applicable only to new applications.

Discussion

Cefic asked for confirmation that all three documents will not apply for ongoing applications and suggested that implementation timelines are included in such documents. The speaker explained that the agreement on the implementation should be available in the public minutes of the CG meeting. The Commission highlighted that the timelines for the implementation of the agreements should be clear for all the stakeholders. The Commission committed to clarify the implementation date of for the CG agreement related to the shelf-life studies.

Action point

The Commission will clarify the date of application on the agreement on post-authorisation conditions related to shelf-life.

1.3 Update from the ECHA Helpdesk

Anisa KASARUHO (Regulatory Support team, ECHA) gave an overview of the type and number of questions received by the ECHA helpdesk in the past year. She also discussed the ongoing BPR projects. In terms of type of questions received, she highlighted a case where a Competent Authority (CA) had questioned the eligibility of a product for simplified authorisation due to the fact that the substance at hand did not meet the classification criteria under Art 28, despite the fact that the substance was included in Annex I. She clarified that Annex I could be amended if the substance had a harmonised classification, otherwise a standard authorisation procedure

could be followed if the Art 25 criteria is not met. In addition, she discussed a Same Biocidal Product (SBP) question explaining that the link to a reference product in an SBP application does not represent confidential information.

Furthermore, ECHA discussed a number of questions related to the expiry of data protection under Article 95(5) of the BPR. It was clarified that at present, there is no indication that COM will extend the data protection period and that after 31 December 2025, prospective applicants can refer to the expired data for product authorisation purposes. It was noted that the Article 95(5) derogation does not cover renewal data, that the data can only be protected once and that the whole substance dataset expires on 31 Dec 2025 regardless of any later data submission that might be required during the course of the evaluation.

Lastly, the speaker outlined the ongoing BPR projects, which included the launch of the quarterly BPR videoconferences, the creation of a webpage describing national requirements and rules applicable during the Art 89 transitional period and the publication of a BPR handbook.

Discussion

Cefic expressed its gratitude to NHDs and ECHA for the creation of the webpage clarifying national rules and requirements applicable during the transitional period. It was highlighted that this information is invaluable for companies. Cefic committed to advertise the webpage via its social media channels in order to raise awareness about its existence. In addition, Cefic also thanked ECHA about the creation of the BPR handbook, which is also very useful for industry. It was clarified that both the handbook and the webpage are already available online.

2. Topics suggested by national helpdesks and observers

2.1 Overview of the BPR guidance development

Claudio PUTZU (ECHA, Active substance unit) provided an update on the progress made with the guidance development. Regarding the drinking water guidance, it was clarified that the guidance provides information on how to assess the impact of water treatment processes on residues of active substances in water. The guidance applies to both approvals and authorisations and it is foreseen to be published by the end of the year.

Regarding the guidance on the assessment of risks to bees from the use of biocides, it was noted that the first draft was finalised in collaboration with EFSA and Member States Competent Authorities, the consultation is on-going in 2023 and the final guidance document is expected to be published in Q1 of 2024. Regarding the Working Group recommendation on "*In situ* generated active substances," it was highlighted the challenge of defining the specification for substances generated from undefined precursors, where the precursors can vary. The speaker updated the audience on revisions covering phys-chem properties, human health and environmental endpoints and that the guidance is to be finalised by the end of the year.

Furthermore, the speaker announced the publication of the guidance on the analysis of alternatives, which took place in early February. Applicants of substances that are candidates for substitution are advised to prepare an analysis of alternatives according to the criteria outlined in the guidance and to submit it according to the agreed implementation deadline. Lastly, it was indicated that the efficacy guidance is undergoing updates that cover both preservative product-types (PT 11 and 12) and antimicrobial resistance for substances and

products. Following ongoing discussions and consultations, publication is foreseen in Q2/Q3 of next year.

Discussion

ECHA asked the speaker about ways that could enable interested parties to remain updated with the progress made in the development of the different guidance documents. The presenter confirmed that the issue of finding the biocides' guidance material in the ECHA website was highlighted by different stakeholders, including Cefic and A.I.S.E. Therefore, a project has been launched to enable parties to have access to a structured overview of the relevant guidance and support material. The project consists of the creation of a database, where it will be possible to easily find the needed guidance material. The project draft proposal has been finalised, the next step will be to consult with CAs and stakeholders to gather their feedback, afterwards, the implementation will start.

2.2 Introduction to the new SPC solution

Chiara PECORINI (ECHA, Horizontal Support in Biocidal Products Unit (D2)) introduced the new SPC solution. She explained that moving from the SPC Editor tool to a IUCLID based solution is a strategic decision in line with the ECHA's IT strategy aiming at enhancing the integration of the IT tools, supporting the re-usability of data and improving maintainability.

She highlighted that the new SPC solution provides the same content as the current SPC editor, but with a different format. There will be a new interface in IUCLID, specifically created to prepare SPC and the generated SPCs will have a IUCLID format (.i6z). The check of the quality of the SPC will be performed through validation rules. It will be possible to create SPCs based on data available in the product dossier and to generate SPC reports. Translations of the IUCLID interface and of the generated reports will be available in all the EU official languages of the Union and in Norwegian and Icelandic. It was noted that the workflows in R4BP 3 will not change. ECHA already organised two testing sessions with volunteers from industry, Member States and the Commission.

The project is on the right track and ECHA foresees to roll out the new SPC solution in Q4 2023. There is already some material available on the SPC Editor webpage, like instructions to adapt internal databases held by different stakeholders to the SPC IUCLID format. More information and supporting documents will be published in due time. ECHA is revising the SPC Q&As and will organise training sessions and webinars. It was highlighted that for the time being, the SPC editor is still in use to prepare SPCs and that the new IUCLID format cannot be yet accepted by R4BP 3. The speaker thanked all the ECHA colleagues involved in the project and the volunteers of the testing session.

Discussion

Cefic wished to confirm that the SPC editor still needs to be used to prepare SPCs. ECHA confirmed that the SPC Editor has to be used to prepare SPCs in .xml format until the new SPC solution is rolled-out and that after the transition into IUCLID, the SPC editor will not have to be used anymore. With the new SPC solution, SPCs will be in IUCLID format. ECHA also explained that SPCs in .xml format belonging to ongoing or closed cases in R4BP 3, would be automatically migrated in IUCLID (.i6x) format. For the files stored locally, the conversion to .i6z format has to be performed manually through the xml import module in IUCLID.

One of the NHDs was interested to know if there would be an option to create the word file from the SPC. ECHA confirmed that it would be done by the report generation function in IUCLID and the reports will be available as .pdf, .rtf and .docx files.

Another NHD asked about the security requirements, especially for the external experts working on the SPC. ECHA clarified that the SPC creation is possible in two ways: either via local installation, or via ECHA Cloud. For ECHA Cloud services, the access is always required through ECHA credentials that are handled by the individual user access.

Another HelpNet member enquired about the quality of the translations and how to handle situations when an eCA notices mistakes in the translations of the SPC in their national languages. ECHA acknowledged that this is already an ongoing issue and invited CAs to contact ECHA via the R4BP 3 functional mailbox or via the ECHA Helpdesk to communicate the mistakes. ECHA will then trigger an internal procedure. The same will apply after the new SPC solution goes live.

CEFIC enquired further on the security topic asking about which data will be accessible for the consultant company when creating an SPC in the ECHA Cloud. ECHA explained that every user has access to the part of the cloud where users' files are stored. If the user grants access to a third party, this company will gain access to the same data. CEFIC asked for further clarification in the situation where the consultant is only hired to prepare the translation of the SPC. ECHA replied that in this scenario, the solution would be to exchange the SPC files outside of the ECHA cloud, since there is no possibility to restrict the access to specific SPC files. Further instructions on this will be prepared by ECHA.

Lastly, another NHD asked about the possibility to have training sessions for CAs. ECHA confirmed that a training opportunity would be offered and the date would be communicated at a later stage.

2.3 The expiry of data protection under Article 95(5) of the BPR – questions, potential consequences and concerns

Camelia MIHAI (Cefic) illustrated the concerns of industry in relation to the expiry of the data protection period under Art 95(5). She firstly introduced the legal provisions that govern data protection for active substances, namely Art 60(2) and the Art 95(5) derogation. She then discussed the type of questions that Cefic is receiving in relation to this topic. Among other questions, industry asks for clarification about the type of data that is subject to the expiry of data protection, whether a possible extension of the Review Programme will have an effect on the data protection expiry, how can applicants refer to the non-protected data, etc.
The speaker argued that Art 95(5) re-introduces free-riding, incompliant sources on the market and impairs the level-playing field leading to an unfair, costless and effortless Art 95 listing. She argued that Art 95(5) creates an unfair treatment for BPR players, noting that this type of provision is not found in other regulations, e.g. REACH, or the Plant Protection Product Regulation, where the data protection provisions in place lead to an equal and fair treatment of all players for any new data submitted at any time.

Discussion

COM noted that it does not share Cefic's view in relation to Art 95(5). COM clarified further by highlighting that the intention of Art 95(5) is to avoid that the data is protected for a disproportionate period of time and avoid the creation of monopolies. She then asked Cefic to elaborate more about its view on the alleged free riding reintroduction and the introduction of incompliant sources on the market. Cefic responded that the introduction of free riding is related to the fact that companies will have the possibility to place products on the market without contributing to the approval costs. Cefic also emphasised that the data submitted later during the course of an evaluation, e.g. generated and submitted after 2015, will not benefit from the 10 years data protection period. In addition, Cefic indicated that incompliant products will be placed on the market as the Art 95 listing will no longer be checked, similarly with what happened with disinfectants placed on the market during the pandemic, when the obligation to comply with Art 95 was temporarily not stringent. COM replied by noting that over the years that the data has been protected, there has been sufficient time to recover the approval costs through all the companies that have purchased a Letter of Access. Regarding the point on incompliant sources, COM noted that Art 95 listing is not a requirement for technical equivalence and that following approval of a substance, the reference specification is set, and where applicable, technical equivalence must be demonstrated. Furthermore, COM noted that there are products that have benefited for a very long protection, even more than 12 years. COM admitted that is difficult to strike a balance on all points, and that it is true that, for example, the data on endocrine disrupting properties will not be protected for a long period of time, however this was already known, and taking everything into account, COM's position is not to amend Art 95(5).

ECHA also shared the view of COM regarding the alleged free-riding claim and the placing on the market of incompliant sources, highlighting that the approval costs should have already been recovered and that the requirement for proving technical equivalence prevents the placing on the market of incompliant sources. Ultimately, COM thanked Cefic for bringing up the topic for discussion and indicated that the points raised are relevant and further reflection is needed on the topic.

COM and the Chair asked NHDs whether they had received questions on this topic. It emerged that, for the time being, this was not the case.

Closing of the BPR Workshop

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

Annex I – Agendas

REACH Workshop

Venue: ECHA, Voima Conference Centre
Chair: Erwin ANNYS

REACH Workshop	
Opening the REACH Workshop	
09:30	Opening by the Chair (ECHA, Erwin ANNYS)
1. Morning session	
09:45	1.1 Update from the European Commission (DG GROW, Miriam STAHLHACKE)
10:15	1.2 Updates on the guidance for intermediates (ECHA, Augusto DI BASTIANO)
Coffee break (10:35-11:00)	
11:00	1.3 Restriction: Per- and polyfluoroalkyl substances (PFAS) restriction proposal (Dossier Submitters, Sweden, Jenny IVARSSON and ECHA, Michael GMEINDER)
12:00	1.4 Requirements for nanoforms in the safety data sheet (Germany, Anja HACKMANN) **Ideas jam** (discussion in smaller groups)
Lunch break (12:45-13:45)	
2. Afternoon session	
13:45	2.1 Updates on monomer and polymers' guidance (ECHA, Laszlo MAJOROS)
14:05	2.2 Waste legislation case study (Slovenia, Simona FAJFAR) **Ideas jam** (discussion in smaller groups)
Coffee break (14:50-15:10)	
15:10	2.3 Applicability of Article 2(7)(d) exemption (Germany, Suzanne WIANDT and ECHA, Amandine JOMIER) **Ideas jam** (discussion in smaller groups)
15:55	2.4 Grouping of substances – challenges identified (Cefic, Amaja JANOSI)
16:15	**Conclusions of the day**
16:30	**End of the first day of meeting**

18th HelpNet Steering Group meeting

Venue: ECHA, Voima Conference Centre
Chair: Erwin ANNYS

18th HelpNet Steering Group meeting	
Opening the Steering Group meeting	
09:30	Opening by the Chair (ECHA, Erwin ANNYS)
09:35	Opening by the Executive Director of ECHA, Dr Sharon MCGUINNESS
09:45	HelpNet 17 - follow-up of action points
09:55	Approval of the HelpNet 18 draft agenda
Updates from the HelpNet Secretariat	
10:00	1.1 ECHA preparing for new tasks (ECHA, Erwin ANNYS)
10:20	1.2 HelpNet update (ECHA, Elena BIGI)
Coffee break (10:40-11:00)	
11:00	1.3 Report on annual activities (ECHA, Amandine JOMIER, Evelyne FRAUMAN)
11:20	1.4 Borderline Working Group - Aggregates assessment (ECHA, Telmo VIEIRA PRAZERES) **Ideas jam (discussion in smaller groups)**
2. Updates on ECHA activities	
11:50	2.1 Update from IT External Support team (ECHA, Peter SIMCIC)
12:10	2.2 Communication activities (ECHA, David CLIFFE)
Lunch break (12:30-13:30)	
13:30	2.3 Forum activities (ECHA, Maciej BARANSKI)
13:50	2.4 Update on dissemination activities (ECHA, Eoin BRENNAN)
Coffee break (14:10-14:30)	
3. Update from candidate countries	
14:30	3.1 An introduction to the work of the Serbian helpdesk (Jelena GRUJIĆ)
14:50	**Conclusions of the day**
4. Training session	
15:05	4.1 HelpEx training (ECHA, Viorica NAGHY, Roxana BROASCA)
16:15	**End of the second day of meeting**

CLP Workshop

Venue: ECHA, Voima Conference Centre
Chair: Erwin ANNYS

CLP Workshop	
Opening the CLP Workshop	
09:30	Opening by the Chair (ECHA, Erwin ANNYS)
1. Updates from the European Commission and ECHA	
09:45	1.1 Update from the European Commission (DG GROW, Svetlana SKRYNIKOVA)
10:15	1.2 How ECHA is preparing for the delegated regulation: guidance, IT tools, support material (ECHA, Konstantinos PREVEDOUROS and Pia KORJUS)
Coffee break (10:45-11:05)	
2. Topics proposed by HelpNet members and observers	
11:05	2.1 How can national helpdesks support companies with information on new harmonised hazard classifications (Sweden, Jonas FALCK)
11:20	2.2 How the German national helpdesk is preparing for the CLP revision (Germany, Anja HACKMANN)
Lunch break (12:00-13:00)	
3. Poison centre notification. Break out session	
13:00	3.1 Annex VIII application date for industrial uses: communication campaign and support (ECHA, Pedro ROSELLÓ VILARROIG)
13:20	3.2 e-liquids: notification duties, advertisement, labelling and enforcement (Cyprus, Maria PALEOMILITOU) **Ideas jam** (discussion in smaller groups)
Coffee break (14:05-14:30)	
4. Training session	
14:30	4.1 Live demonstration on the ECHA submission portal for poison centre notification (PCN) (ECHA, Pedro ROSELLÓ VILARROIG)
15:15	**Conclusions of the day**
15:30	**End of the third day meeting**

BPR Workshop

Venue: ECHA, Sisu Conference Centre
Chair: Elena BIGI

BPR Workshop	
Opening the BPR Workshop	
09:30	Opening by the Chair (ECHA, Elena BIGI)
1. Updates from the European Commission and ECHA	
09:45	1.1 Update from the European Commission (DG SANTE, Ligia NEGULICI)
10:15	1.2. Legal update (ECHA, Valeria D'AGOSTINI)
Coffee break (10:35-11:00)	
11:00	1.3. Update from the ECHA Helpdesk (ECHA, Anisa KASARUHO)
2. Topics suggested by national helpdesks and observers	
11:20	2.1 Overview of the BPR guidance development (ECHA, Claudio PUTZU)
11:40	2.2 Introduction to the new SPC solution (ECHA, Chiara PECORINI)
Lunch break (12:10-13:15)	
13:15	2.3 The expiry of data protection under Article 95(5) of the BPR – questions, potential consequences and concerns (Cefic, Camelia MIHAI)
13:45	**Conclusions of the day**
14:00	**End of the third day meeting**

Annex II - Action points

REACH workshop

No.	Action	Agenda item	Who	Status
1.	European Commission to update HelpNet on the impact of the CTAC Application for Authorisation (AfA) annulment.	1.1	European Commission/ ECHA	Open
2.	ECHA will share the link of the Forum enforcement project of authorisation - REACH-EN-FORCE-9 (REF-9) and presentations of the workshop.	1.1	ECHA	Closed
3.	ECHA to share guidance process document with HelpNet members.	1.2	ECHA	Closed
4.	ECHA to check if it is needed to reopen HelpEx ID 2045 based on revised guidance for monomers and polymers.	2.1	ECHA	Closed
5.	Topic for next REACH Workshop in November 2023: Substance sameness in the context of recovered substances.	2.3	ECHA	Open

18th HelpNet Steering Group meeting

No	Action	Agenda item	Who	Status
1.	Annual report on questions redirected to NHDs will be provided by the end of the year with details on countries' redirection. Slides with the countries' details will be also added to the current presentation.	1.2	ECHA	Ongoing
2.	Consider the possibility to link the restrictions' texts in national languages on the 'Substances restricted under REACH' online list available on ECHA's webpage at: https://echa.europa.eu/substances-restricted-under-reach	1.2	ECHA	Open
3.	Consider how to harmonise the collection of data from NHDs in our annual survey/report.	1.3	ECHA	Open
4.	Launch a written procedure on the conclusion of the BWG for recovered aggregates and the need to review the guidance on waste and recovered substances.	1.4	ECHA	Ongoing
5.	ECHA will inform the HelpNet on the result of Forum discussion on TARIC codes for REACH restrictions.	2.3	ECHA	Open

CLP workshop

No.	Action	Agenda item	Who	Status
1.	ECHA to consult internally if ED, PBT properties can be shown already in the C&L inventory	1.2	ECHA	Closed
2.	HelpNet Secretariat to share the slides of IPA Information session on CLP[20].	2.2	ECHA	Closed
3.	HelpNet Secretariat to keep NHD up to date about communication campaign for PCN compliance date, in particular webinar in November.	3.1	ECHA	Closed
4.	NHD to promote webinar in November once this is published.	3.1	NHD	Ongoing
5.	Germany to post in HelpEx their Q&A on tobacco products.	4.2	Germany	Ongoing
6.	Propose to Forum a project on tobacco-like products.	4.2	NHDs	Ongoing

BPR workshop

No	Action	Agenda item	Who	Status
1.	To clarify the date of application on the agreement on post-authorisation conditions related to shelf-life.	1.2	Commission	Open

[20] Available for HelpNet members and observers in the collaboration platform (S-CIRCABC) at:
Path: /CircaBC/echa/HelpNet/Library/01 Collaboration/CLP/CLP info session_IPA
Browse url: https://webgate.ec.europa.eu/s-circabc/w/browse/e286384f-deae-4ef5-8c2a-dd2cb39134e7

Annex III – List of participants

REACH workshop

Country	Name
Austria	Barbara WETZER
	Stephanie CASTAN (remote)
Belgium	Daphné HOYAUX (remote)
Bulgaria	Margarita GAIGUROVA
Cyprus	Maria ORPHANOU
	Maria PALEOMILITOU (remote)
Croatia	Tajana KOVAČEVIĆ
Czech Republic	Jarmila SLADKOVA (remote)
Denmark	Maria THESTRUP JENSEN
Estonia	Anna AMELKINA
Finland	Sari TUHKUNEN
	Mervi ASSMANN (remote)
France	Gaëlle DUFFORT
	Nathalie HAYAUD
Germany	Anja HACKMANN
	Suzanne WIANDT
	Angelina GADERMANN (remote)
	Claus HAAS (remote)
	Heinz BUELTER (remote)
Greece	Eleni FOUFA (remote)
Hungary	Tamas KOVAC
Ireland	Majella COSGRAVE
	Margarete HOULIHAN (remote)
Italy	Francesca CARFI
	Sabrina MORO IACOPINI (remote)
Latvia	Elīna LAZDEKALNE
Lithuania	Beata VOLUJEVIC
	Agne JANONYTE (remote)
	Jurgita BALCIUNIENE (remote)
Luxembourg	Ghaya RZIGA
	Laurène CHOCHOIS
Netherlands	Margaretha WOUTERS
Norway	Cecile BLOM
Portugal	João ALEXANDRE
Romania	Nicoleta CAROLE
	Maria MIJA (remote)
Slovakia	Anna SLIMÁKOVÁ

	Karol BLESAK (remote)
Slovenia	Simona FAJFAR
Spain	Ángela SÁNCHEZ CONDE
	Laura ZAMORA NAVAS (remote)
Sweden	Jenny Sophie VIRDARSON
	Helena DORFH (remote)

European Commission

DG	Name, surname
DG GROW	Miriam STAHLHACKE

Candidate countries observers

Country	Name, surname
Montenegro	Jelena KOVACEVIC
	Nevena BOGAVAC
	Tatjana MUJIČIĆ
Serbia	Bojana DORDEVIC
	Jelena GRUJIC
	Snezana JOKSIMOVIC
Türkiye	Bektas KILIC
	Ferat GUREN
	Okan KUMCU

Industry observers

Organisation	Name, surname
A.I.S.E.	Jan ROBINSON (remote)
	Julie JANSSIS (remote)
Cefic	Amaya JANOSI
EDANA	Alexander HEUSCH (remote)
ORO	Jan NYLUND

ECHA staff

Unit[21]	Name, surname
A2	Amandine JOMIER
	Anita TUOMAINEN
	David CLIFFE
	Elena BIGI
	Eduardo BARRETO TEJERA
	Erwin ANNYS
	Evelyne FRAUMAN
	Laure PAIN
	Maciej BARANSKI
	Malgorzata SZKLAREK
	Pedro ROSELLÓ VILLAROIG
	Roxana BROASCA
	Ruben GONZALEZ VIDA
	Peter SIMCIC
	Severine SOSINGOT
	Viorica NAGHY
A4	Eoin BRENNAN
B1	Laszlo MAJOROS
B1	Pertti ELO
B1	Rossella DEMI
B3	Anne-Mari KARJALAINEN
B3	Mark BLAINEY
B4	Telmo Jorge VIEIRA PRAZERES
D3	Augusto DI BASTIANO
D4	Michael GMEINDER
E2	Cyril JACQUET
	Fausto COMANDE
R3	Ari VALKEINEN
	Irene PALOMINO LEO
	Konstantinos ANAGNOSTAKIS
	Lina NIKOLAJEVA
	Marko POPOVIC
	Taru NIEMINEN
	Teuvo HONKAKUNNAS

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

HelpNet Steering group meeting

Country	Name
Austria	Barbara WETZER
	Peter SCHINDLER
	Stephanie CASTAN
Belgium	Kristof CLAES
	Daphné HOYAUX (remote)
Bulgaria	Margarita GAIGUROVA
Cyprus	Maria PALEOMILITOU (remote)
	Maria ORPHANOU
Croatia	Irena Zorica JEŽIĆ VIDOVIĆ
	Ivana VRHOVAC FILIPOVIC
	Tajana KOVAČEVIĆ
Czech Republic	Jan KOLAR
	Jarmila SLADKOVA (remote)
Denmark	Line Schmidt KOLDING
	Maria THESTRUP JENSEN
	Lone KÆRGAARD
Estonia	Aigi LAHE
	Anna AMELKINA
	Riina LAHNE
Finland	Hannu MATTILA
	Sari TUHKUNEN
France	Nathalie HAYAUD
	Gaëlle DUFFORT
Germany	Anja HACKMANN
	Oliver Michael BRYLSKI
	Suzanne WIANDT
	Angelina GADERMANN (remote)
	Heinz BUELTER (remote)
Greece	Eleni FOUFA (remote)
Hungary	Henrietta HAGYACKIJ-SZABÓ
	Tamas KOVACS
Ireland	Majella COSGRAVE
	Louise PIERCE (remote)
	Margarete HOULIHAN (remote)
Italy	Francesca CARFI
	Maria ALESSANDRELLI
	Sonia D'ILIO (remote)
Lithuania	Agné JANONYTÉ

	Beata VOLUJEVIČ
	Jurgita BALČIŪNIENĖ (remote)
Luxemburg	Ghaya RZIGA
	Laurène CHOCHOIS
	Jeff ZIGRAND (remote)
Latvia	Elina LAZDEKALNE
	Evija PORIĶE
	Sandra MATĪSA
Malta	Nathanael ELLUL (remote)
Netherlands	Evan BEIJ
	Femke VAN DRIESTEN
	Floris GROOTHUIS
	Margaretha WOUTERS
Norway	Cécile BLOM
	Karina PETERSEN
	Sunniva Helene FRØYLAND
Poland	Agnieszka Eliza BARANOWSKA-MOREK
Portugal	Isabel LAGINHA
	João ALEXANDRE
Romania	Nicoleta CAROLE
	Mihaela Simona DRAGOIU
	Maria MIJA (remote)
Slovak Republic	Anna SLIMÁKOVÁ
	Gabriela TOMKOVA
	Jadža PORUBIAKOVÁ
	Lucia MURÁNIOVÁ (remote)
	Maria SKULTETYOVA (remote)
	Katarina BURANOVA (remote)
	Karol BLESAK (remote)
Slovenia	Marta PAVLIČ ČUK
	Simona FAJAR
	Tatjana HUMAR-JURIČ
Spain	Ángela SÁNCHEZ CONDE
	David CANO GOMEZ
	Laura ZAMORA NAVAS (remote)
Sweden	Inger Anneli RUDSTRÖM
	Jonas FALCK
	Helena DORFH (remote)
	Jenny VIRDARSON

Candidate countries observers

Country	Name, surname
Montenegro	Jelena KOVACEVIC
	Nevena BOGAVAC
	Tatjana MUJIČIĆ
Serbia	Bojana DORDEVIC
	Jelena GRUJIC
	Snezana JOKSIMOVIC
Türkiye	Bektas KILIC
	Ferat GUREN
	Okan KUMCU

Third country observers

Country	Name, surname
Switzerland	Markus HOFMANN (remote)
	Olivier BLASER (remote)

Industry observers

Organisation	Name, surname
A.I.S.E.	Giulia SEBASTIO (remote)
Cefic	Amaya JÁNOSI
	Camelia MIHAI
ORO	Jan NYLUND

ECHA staff

Unit[22]	Name, surname
D0	Sharon MCGUINNESS
A1	David CLIFFE
A2	Erwin ANNYS
	Amandine JOMIER
	Anisa KASARUHO
	Eduardo BARRETO TEJERA

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

	Elena BIGI
	Evelyne FRAUMAN
	Gary WATKINS (remote)
	Malgorzata SZKLAREK
	Maciej BARANSKI
	Pedro ROSELLÓ VILARROIG
	Ruben GONZALEZ VIDA (remote)
	Roxana BROASCA
	Severine SOSINGOT (remote)
	Viorica NAGHY
R3	Ari VALKEINEN
	Daniel NYGARD
	Dobromir DOSKACHAROV
	Irene PALOMINO LEO
	Konstantinos ANAGNOSTAKIS
	Lina NIKOLAJEVA
	Marko POPOVIC
	Taru NIEMINEN
	Teuvo HONKAKUNNAS

CLP workshop

Country	Name, surname
Austria	Barbara WETZER
	Stephanie CASTAN
Belgium	Kristof CLAES
Bulgaria	Margarita GAIGUROVA
Croatia	Irena Zorica JEŽIĆ VIDOVIĆ
Cyprus	Maria PALEOMILITOU (remote)
Czech Republic	Jarmila SLADKOVA (remote)
Denmark	Toke THOMSEN
	Henrik SVENSTRUP (remote)
Estonia	Aigi LAHE
Finland	Tapio SALONEN
France	Gaëlle DUFFORT
	Nathalie HAYAUD
Germany	Anja HACKMANN
	Suzanne WIANDT
Greece	Eleni FOUFA (remote)

Country	Name, surname
Hungary	Tamas KOVACS
Ireland	Majella COSGRAVE
	Margarete HOULIHAN (remote)
Italy	Maria ALESSANDRELLI
	Sonia D'ILIO (remote)
Latvia	Sandra MATĪSA
Lithuania	Agnė JANONYTĖ
Luxembourg	Ghaya RZIGA
	Laurène CHOCHOIS
Netherlands	Femke VAN DRIESTEN
Norway	Sunniva Helene FRØYLAND
Portugal	Isabel LAGINHA
Romania	Nicoleta CAROLE
	Maria MIJA (remote)
Slovakia	Gabriela TOMKOVA
	Lucia MURANIOVA (remote)
Slovenia	Tatjana HUMAR JURIČ
Spain	Elena SANCHEZ (remote)
	Laura ZAMORA NAVAS (remote)
Sweden	Jonas FALCK
	Susanna NORRTHON RISBERG (remote)

European Commission

DG	Name, surname
DG GROW	Svetlana SKRYNIKOVA (remote)
DG ENV	Aléxandros KIRIAZIS (remote)

Candidate countries observers

Country	Name, surname
Montenegro	Jelena KOVACEVIC
Serbia	Bojana DORDEVIC
	Snezana KOVACEVIC
Türkiye	Bektas KILIC

Third Country observers

Country	Name, surname
Switzerland	Markus HOFMANN (remote)

Industry observers

Organisation	Name, surname
A.I.S.E.	Jan Robinson (remote)
Cefic	Liisi DE BACKER (remote)
ORO	Satu SALOMÄKI (remote)

ECHA staff

Unit[23]	Name, surname
Support and Enforcement	Amandine JOMIER
	Anita TUOMAINEN
	Eduardo BARRETO TEJERA
	Erwin ANNYS
	Pedro ROSELLÓ VILLAROIG
Submission and processing	Daniele APE
	Saara SUMIALA
Corporate services	Ari VALKEINEN
	Irene PALOMINO LEO
	Konstantinos ANAGNOSTAKIS
	Lina NIKOLAJEVA
	Marko POPOVIC
	Taru NIEMINEN
	Teuvo HONKAKUNNAS

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

BPR workshop

Country	Name, surname
Austria	Peter SCHINDLER
Croatia	Ivana VRHOVAC FILIPOVIC
Czech Republic	Růžena BEDNAŘÍKOVÁ (remote)
Denmark	Line SCHMIDT KOLDING
	Lone KÆRGAARD
	Nicholai D JENSEN (remote)
Estonia	Riina LAHNE
Finland	Hannu MATTILA
Germany	Oliver Michael BRYLSKI
Greece	Vasileios VAGIAS
Hungary	Henrietta HAGYACKIJ-SZABÓ
Ireland	Louise PIERCE (remote)
	Mervyn PARR (remote)
Italy	Renato CABELLA (remote)
Latvia	Evija PORIKE
Luxembourg	Jeff ZIGRAND (remote)
Netherlands	Cindy VAN DER MEER
Norway	Karina PETERSEN
Poland	Agnieszka BARANOWSKA-MOREK
Romania	Mihaela-Simona DRĂGOIU
Slovak Republic	Jadža PORUBIAKOVÁ
Slovenia	Marta PAVLIČ ČUK
Spain	David CANO GOMEZ
Sweden	Inger Anneli RUDSTRÖM

European Commission

DG	Name, surname
DG SANTE	Ligia NEGULICI

Third Country observers

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

Industry observers

Organisation	Name, surname
Cefic	Camelia MIHAI
ORO	Jan NYLUND

ECHA staff

Unit[24]	Name, surname
A2	Anisa KASARUHO
	Elena BIGI
	Evelyne FRAUMAN
	Malgorzata SZKLAREK
	Roxana BROASCA
E2	Valeria D'AGOSTINI
D1	Claudio PUTZU
D2	Chiara PECORINI
R3	Ari VALKEINEN
	Irene PALOMINO LEO
	Konstantinos ANAGNOSTAKIS
	Lina NIKOLAJEVA
	Marko POPOVIC
	Taru NIEMINEN
	Teuvo HONKAKUNNAS

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