# HelpNet REACH and CLP Workshop – WebEx session 8 June 2021

## Summary of discussions

The HelpNet REACH and CLP Workshop, organised for the REACH and CLP members and observers of the HelpNet, took place on 8 June 2021 by web conference. The afternoon sessions were open for observers from potential candidate and third countries, and industry.

This document summarises the topics discussed during the workshop (Annex I) and the follow-up action points set (Annex II). The summary of the sessions dedicated to REACH and CLP members only will not be published on ECHA's website but will be shared in S-CIRCABC[1]. The session addressing topics proposed by ECHA and national helpdesks (NHDs) will be published on ECHA's website[2]. The list of participants is available in Annex III.

## Opening of the REACH and CLP Workshop

**The Chair of the HelpNet, Erwin ANNYS** (ECHA) opened the REACH and CLP Workshop and welcomed representatives of the NHDs, observers from potential candidate and third countries, and industry who registered for the event. The Chair introduced the agenda of the day, which was adopted without further comments.

## 1. Division of competences between ECHA and national REACH and CLP helpdesks [IN CLOSED SESSION]

## 2. Building competences in the REACH helpdesks [IN CLOSED SESSION]

## 3. REACH topics proposed by national helpdesks and ECHA

### 3.1 Update on nanoforms: from registration to evaluation and nanomaterials expert group

Abdelqader SUMREIN, Amaia RODRIGUEZ-RUIZ and Frank LE CURIEUX (ECHA) gave an update on nanomaterials from registration to evaluation, and information about the Nanomaterials Expert Group, respectively.

Abdelqader SUMREIN briefly summarised the REACH requirements for nanomaterials applying as of 1 January 2020, covering all new and existing registrations for nanoforms when the total registration tonnage of the substance (whether as nanoform or non-nanoform) is above one tonne per registrant.

The speaker presented the new REACH information requirements for nanomaterials requiring companies to provide enough information to demonstrate the safe use of their nanoforms for human health and the environment and concern:

[1] REACH and CLP Workshops (8-9 June 2021) folders: Path: /CircaBC/echa/HelpNet/Library/02 Steering Group/Workshops/REACH and CLP Workshops (8-9 June 2021)
[2] https://echa.europa.eu/about-us/partners-and-networks/helpnet/2021

- Annex VI – characterisation of nanoforms or sets of nanoforms covered by the registration;
- Annex VII-X – standard information requirements specific for each nanoform/set of nanoforms; and
- Annex VII-X – modifications/additions concerning information requirements for nanoforms

Abdelqader SUMREIN mentioned that 86 registrations[3] for 34 substances covering nanoforms were received by 1 January 2020. After one year and a half, the number of unique submissions increased to 384, with a total of 122 different substances successfully registered so far and 361 submissions passing the technical completeness check (TCC). Examples on lead dossiers/substances with TCC complete datasets and the top 10 substances based on the number of dossiers were given.

Amaia RODRIGUEZ-RUIZ presented the main learnings from experience gained in 2020, which showed that determining the validity of sets of similar nanoforms/characterisers of nanoforms (as per Annex VI) is a prerequisite for the assessment of the corresponding information under Annex VII-X. Moreover, clarity on the characterisers of what has been registered is needed to understand the validity and adequacy of studies provided under Annex VII-X.

ECHA would follow a two-tier approach:

- Step 1: compliance checks targeted on Annex VI – assessing the compliance on characterisation requirements set out in Annex VI for each reported nanoform or set of nanoforms.
- Step 2: compliance checks of Annex VII-X – standard information requirements once Annex VI is clear.

When an information requirement cannot be met with existing data or adaptations, and the test method for nanomaterials is under development, registrants are advised to provide:

- a testing proposal in the corresponding IUCLID section and justifications for why alternative methods cannot be used (vertebrate animals) – for Annex IX and X information requirements;
- a temporary derogation with the commitment to initiate testing as soon as test guidelines are available – for Annex VII and VIII information requirements.

Regarding the evaluation process, two compliance checks (targeted at Annex VI) were planned in 2021: multi-wall carbon nanotubes (MWCNT), and titanium dioxide ($TiO_2$). The substance evaluation on MWCNT was concluded in 2020 with the outcome of ECHA to perform a compliance check, while the substance evaluation of $TiO_2$ was under the decision-making process.

Amaia RODRIGUEZ-RUIZ mentioned that until 8 June, ECHA has received testing proposals for six substances containing nanoforms, from which five are on the nanoform of the substance.

The European Union Observatory for Nanomaterials[4] (EUON) offers a summary of the revised REACH annexes and updated list of test guidelines[5], or ongoing test guideline developments relevant for the safety testing of nanomaterials under the REACH Regulation.

[3] The registration statistics were covering registration dossiers submitted to ECHA from 1 November 2019 until 25 May 2021.
[4] https://euon.echa.europa.eu
[5] https://euon.echa.europa.eu/reach-test-methods-for-nanomaterials

Frank LE CURIEUX gave an update on the activity of the Nanomaterial Working Group (NMWG) established in 2012 when the EU recommendation on the definition of nanomaterials was just published and there was no specific reference to nanomaterial/nanoform in REACH and no explicit requirements for nanomaterials under REACH or CLP.

The NMWG was created to discuss scientific and technical questions on nanomaterials relevant to REACH and CLP. The group brings together about 40 external experts[6] from EU Member State competent authorities, European Commission, European Food Safety Authority (EFSA), stakeholder organisations and industry associations, as well as non-governmental organisations.

The speaker highlighted the main contributions of the NMWG on general topics and specific cases, contributing to a good dialogue between industry and ECHA and supporting the preparation of ECHA guidance documents on nanoforms/nanomaterials.

Since 2017, the name changed to **N**anoMaterials **E**xpert **G**roup[7] (NMEG) to align with the Persistent, Bioaccumulative and Toxic (PBT) Expert Group[8] and Endocrine Disruptor Expert Group[9]. The mandate of the group was also updated in 2021 to focus its activities more on discussions directly relevant for ECHA processes (REACH, CLP, BPR) and EUON.

### Discussion

On questions regarding the registration dossiers received, ECHA clarified that single nanoforms or a set of nanoforms or a combination of the two could be found in the same registration dossier. It was highlighted that when the derogation to register various nanoforms under one set of nanoforms is used, the dossier needs to include a scientific justification addressing each different aspect of the characterisation of the nanoforms (e.g. surface active treatment, different particle size distribution, specific surface area); this allows the hazard, exposure and risk assessment to be done jointly. However, it was too early for ECHA to specify the criteria that the registrants were following to justify that the hazard, exposure and risk assessment within a set of nanoforms could be performed jointly.

One substance can have one or several forms (e.g. several nanoforms and non-nanoform), and all of them need to be registered, either as single nanoforms or by derogation as sets of nanoforms. Registrants decide the amount of sets of similar nanoforms or single nanoforms they register based on the amount of forms and the information they have on them, which may vary greatly. By June 2021, ECHA received registration dossiers with a range from a single set of nanoforms to 12. Some companies were registering individual nanoforms as well.

## 3.2 Considerations on the substance definition in a regulatory context

Claus HAAS from the German helpdesk (BAuA) presented some reflections on the concept of substance and how it has evolved since the Dangerous Substances Directive across several pieces of EU chemicals legislation.

In this context, the German helpdesk published a document 'Considerations on the concept of substance in European substance legislation'[10] addressing the development of the substance definition in a regulatory context, which introduces additional concepts to the substance

[6] https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group/members
[7] https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group
[8] https://echa.europa.eu/pbt-expert-group
[9] https://echa.europa.eu/endocrine-disruptor-expert-group
[10] Publication available in German on the helpdesk website: https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Publikationen/DE/REACH/BAuA/Fachbeitraege/Fokus_REACH_Stoffbegriff.html

definition under REACH and CLP, as follows:

- 'Real substance': a substance, as produced, following the definition in Article 3(1) of REACH;
- 'Ideal substance': any constituent of a real substance defined by its structural formula, molecular formula, chemical name and numerical identifiers (e.g. CAS numbers). This concept is currently limited to well-defined substances; UVCBs may require additional considerations.

The speaker provided their reflections on different applications of the substance definition in the legal text and the corresponding regulatory requirements, as described in the publication. While Articles 5, 6 and 56 of REACH and Article 39 of CLP imply an interpretation that would correspond to the Article 3(1) substance definition ('real substance'), certain substance lists, such as the EINECS list, the Authorisation List (Annex XIV to REACH) and Annex VI to CLP would correspond to lists of 'ideal substances'.

Moreover, Articles 11(1) and 11(2) to REACH imply the use of both 'real' and 'ideal' substance definitions. It was mentioned that this apparent mismatch of the application of the substance definition has consequences on substance sameness, data sharing, read across, dossier/substance evaluation, Candidate List obligations and authorisation requirements, among other processes of REACH and CLP.

Claus HAAS concluded his presentation suggesting a consideration of introducing the concept of 'real substance' vs 'ideal substance' in the context of the future REACH and CLP revision, and highlighted the importance of a legal specification of the substance definition as a prerequisite for adequate risk management.

## 3.3 Obligations for lead and its compounds in articles

Heinz BÜLTER from the German helpdesk (BAuA) presented an example of a new publication format issued by the German helpdesk, 'Pflichten zu Blei und dessen Verbindungen in Erzeugnissen'[11]. The publication, addressing obligations regarding lead and its compounds in articles, is available in German on the helpdesk website.

Heinz BÜLTER noted that most helpdesk enquiries regarding SVHCs present in articles are related to lead and concern the relevant REACH obligations and the interface with other EU chemicals legislation.

The publication is structured in three parts:

- Part I contains information on the obligations under REACH: notification obligation (Article 7(2)), communication obligation (Article 33(1),(2)) and restrictions;
- Part II includes considerations of the borderline of REACH with article-related provisions under other EU chemicals legislation (RoHS, Toys Directive, CE labelling, WFD);
- Part III illustrates four examples (import of jewellery, import of cabinets etc.) and step-by-step considerations in determining the obligations that apply in each case.

The information materials produced by BAuA and ECHA vary based on the detail and scope of information. The new format of BAuA publications, 'Helpdesk kompakt', is addressing special topics that would exceed one or more frequently asked questions and can be presented within a few illustrated pages. It has been used for other topics, as for example 'Substances in need of regulation: identification and appropriate measures' (only German) and 'How to apply the harmonised classification of titanium dioxide?' (in German and English).

[11] https://www.baua.de/DE/Angebote/Publikationen/Praxis/Blei.pdf?__blob=publicationFile&v=5

## Discussion

In his intervention, Augusto DI BASTIANO (ECHA) noted that the topic was raising similar issues as discussed in the 'More than One Constituent Substances' (MOCS) working group (previously 'UVCB task force') and invited the speaker to consider the discussions ongoing in the context of the working group on MOCS to avoid duplicating efforts and to send univocal messages to external stakeholders on this complex topic.

Claus HAAS responded that they are aware of the activity of the working group and are considering combining their activities in this topic area with the work of the MOCS group, of which Germany is an active member.

Michal SKOWRON (ECHA) asked how Germany would approach the multi-constituent substances and the boundary composition concept.

Claus HAAS clarified that the intention was to first introduce and clarify the concept of real substance versus ideal substance for well-defined substances and then enlarge it with more complex substances (UVCB substances; MOCS WG), including the boundary composition defined in a joint submission.

## 3.4 SCIP overview

Helena JÄRNSTRÖM and Clara RUEDA gave an overview of the SCIP[12] activities, with figures on the incoming data and initial lessons learned, how ECHA would make the data available and the SCIP questions received so far by ECHA.

SCIP was established under the Waste Framework Directive (WFD) to ensure that the information on substances of very high concern (SVHCs) is available throughout the whole lifecycle of products and materials, including at the waste stage and to reduce SVHC content in materials and products, including recycled materials.

SCIP provides transparency towards waste operators (e.g. disassembly, recycling) and consumers of products containing harmful chemicals. The SCIP database will track harmful chemicals which is key for moving towards a more circular economy.

The notification obligation applies as from 5 January 2021 to companies placing articles containing SVHCs from the Candidate List on the EU market above 0.1% w/w. These articles can be produced in the EU or imported from non-EU countries. The notification obligation does not apply to retailers regarding articles they only supply directly to consumers, unless they also import those articles.

The revised Waste Framework Directive 2008/98/EC, which entered into force in July 2018, provided a role for ECHA to establish and maintain a database with information on articles containing SVHCs on the Candidate List. The information to be provided to ECHA, according with the European Commission, in a SCIP notification has to include:

- information that allows the article to be identified;
- the identification of the Candidate List substance in the article, its concentration range and its location, as appropriate; and
- any other information on the safe use of the article, available to the supplier, notably information which is necessary to ensure proper management of the article once it becomes waste.

[12] **S**ubstances of **C**oncern **I**n articles, as such or in complex objects (**P**roducts).

ECHA has developed IT tools to help duty holders to prepare and submit the information above. Information about the harmonised IUCLID format for preparing SCIP notifications is available on the dedicated SCIP format web page[13]. Companies can create SCIP notification dossiers:

- online, using IUCLID Cloud maintained by ECHA;
- offline, using the IUCLID 6 (Server & Desktop);
- using the company's own IT infrastructure to prepare a dossier according to the harmonised format defined by ECHA.

Companies can submit the notification using the ECHA Submission Portal from the IUCLID Cloud, by accessing the portal and uploading the dossier manually or using the System-to System (S2S) service available to support companies that wish to prepare and submit SCIP notification dossiers in an automated way.

ECHA was expecting a high number of submissions and received 12 708 007 submissions from 26 October 2020 to 10 May 2021. This was a very high volume compared with any other processes at ECHA.

However, different submissions could be related with the same article notification. ECHA received 8 859 367 SCIP notifications. The number of legal entities from the 27 Member States that were responsible for those notifications was 4 486. ECHA was expecting a higher number of legal entities, as this obligation covers a broad range of different actors of the supply chain.

ECHA will publish the information, as received, on its website. The quality of the data remains the responsibility of each duty holder. At the same time, ECHA implemented and is implementing several mechanisms to ensure the protection of confidential business information where justified, namely concerning the links between the actors in the supply chain. For example, the name of the submitters is not disclosed and the required data which could allow links between actors in the same supply chain to be established will not be made publicly available (identifiers such as the brand and the model of components in complex objects is not disclosed).

To understand which information would be made publicly available on ECHA's website and what are the principles defined to protect confidential information, duty holders are invited to consult the document 'Dissemination and confidentiality in the SCIP Database'[14].

So far, ECHA has received ~1 400 regulatory questions on SCIP. The following summarises the re-occurring questions:

- Duty holders - Who needs to notify? (Q&A 1609). The EU company - importer, producer, assembler, distributor - needs to assess if they 'supply or make the product available to a third party' when determining their obligations under SCIP.
- Each duty holder (importer, producer, assembler, distributor) needs to submit a notification.
- A duty holder can assign a 'foreign user' (third party) to submit the notification through the duty holder's account (Q&As 960 and 1610).
- The duty holder is responsible for the information submitted to SCIP even when the foreign user feature is used.

Simplifying submissions:

- 'Referencing' and 'Simplified SCIP notification' (SSN) tools have been developed by ECHA to support (simplify) submissions in the supply chain (Q&As 1696 and 1777).

[13] https://echa.europa.eu/tools
[14] https://echa.europa.eu/documents/10162/28213971/dissemination_confidentiality_scip_en.pdf/e0efbea1-d8ec-b67c-de8f-1838b480db6d

- The document 'Tools to refer to SCIP data already submitted to ECHA'[15] describes the technical solutions that can be used by suppliers of articles (e.g. distributors, assemblers) to refer to data already submitted to ECHA by other duty holders.
- Every duty holder receives a SCIP number for their submission, i.e. the SCIP number allocates a notification to the duty holder for the concerned article placed on the market (article as such or complex object). Also, the use of the referencing tools is voluntary, but recommended to reduce the amount of data in the database.

Similar articles can be submitted in the same notification:

- Grouping of 'quasi-identical' articles/complex objects in the same notification is possible and recommended. This is described in the document 'Requirements for SCIP notifications'.[16]

Enforcement and fees:

- The WFD will be transposed into the national law of each EU Member State, the enforcement of which is the responsibility of those Member States (Q&A 1611).
- Submitting data on the SCIP database is not invoiced. In other words, users are not charged for the usage of IUCLID, the system-to-system (S2S) submission solution or the SCIP software related to the SCIP database and ECHA does not issue invoices related to SCIP database submissions.

The following links provide support material that ECHA has developed for SCIP:

- https://echa.europa.eu/scip
- https://echa.europa.eu/scip-support
- https://echa.europa.eu/support/qas-support/browse

Lastly, Helena JÄRNSTRÖM introduced the SCIP handbook which would be available for HelpNet members and observers in S-CIRCABC, after the meeting.

## Discussion

According to the annual survey on 2020 activities, SCIP questions were answered by 15 NHDs. ECHA raised the question if the ECHA Helpdesk can refer to these NHDs if a requester asks for national support. Helena JÄRNSTRÖM clarified that some customers have asked if they can contact a specific helpdesk and pointed out that the SCIP questions will still be replied by ECHA

On the question how does a waste operator using complex waste streams find a specific article in the SCIP database, Clara RUEDA clarified that ECHA is expecting that operators would not look for a specific article, but instead for waste streams, e.g. bicycles or materials. Based on the components it is not possible to look for a specific tyre in a bicycle, because ECHA cannot allow links within the supply chain. However, when the component is imported only for a use, the supplier of that component should submit information to the SCIP database, according to the current interpretation.

Regarding how the role of the importer is interpreted, it was mentioned that the question was pending with the Commission. Only retailers supplying directly to consumers are excluded from

[15] Tools to refer to SCIP data already submitted to ECHA (August 2020): https://echa.europa.eu/documents/10162/13567/tools_to_refer_to_already_submitted_sip_data_en.pdf
[16] Requirements for SCIP notifications (October 2020): https://echa.europa.eu/documents/10162/28213971/information_requirements_for_scip_notifications_en.pdf

notification obligations. Concerning spare parts placed on the market, they are not exempted from the notification obligation.

Telmo Jorge VIEIRA PRAZERES clarified the scope of:

- Article 7(2) - two specific exceptions applying when: a) substances are already registered for that use and b) when a company can exclude exposure of the release of the substance from the article (REACH Art. 7(3) and 7(6));
- Article 33 (1) obligations.

One of the competent authorities replying to SCIP questions asked if the SCIP handbook will be shared with the waste operators or colleagues in the Member States replying to SCIP questions. ECHA would consider whether to publish the handbooks on ECHA's website and would come back with an answer by autumn.

ECHA would disseminate the data notified on ECHA's website as received. However, discussions have started with waste operators and NGOs, and dissemination of aggregated data might be considered in the future.

## Conclusions of the day

**The Chair** gave a short wrap-up of the meeting, thanking participants and presenters for their active and valuable contributions to the meeting. He then informed that the action points and the SCIP handbook would be available shortly in S-CIRCABC.

The HelpNet members and observers were invited to register to ECHA's Safer Chemicals Conference organised on 6 October as a free online event for up to 2 500 external stakeholders. Registration starts on 6 August 2021. The full conference programme is available on the event page: https://echa.europa.eu/fi/-/safer-chemicals-conference

ECHA is experimenting with a new online event platform with multiple interactive areas – including sessions with live Q&A, a virtual exhibition, and speed networking. Participants can move in and out of rooms just like in a physical event. The conference will focus on helping companies become more sustainable and preparing them for the new EU obligations.

The ECHA helpdesks – REST and iTEX – are hosting the stand: 'Get support: meet the helpdesks'. The helpdesks aim to use this event to explain to companies the division of competences between ECHA and NHDs and novelties (e.g. new contact forms, non-EU customers now also have to contact NHDs, etc).

The Chair also informed about the surveys, the usual satisfaction survey and, in addition, a written procedure to be launched to seek NHDs' opinion and their final agreement on the new division of competences and ways of working between ECHA and the REACH and CLP NHDs.

HelpNet members and observers were informed that the 16th HelpNet Steering Group meeting and regulatory workshops would take place from 2 to 5 November 2021.

# HelpNet CLP Workshop - WebEx session

# 9 June 2021

## Summary of discussions

## Opening of the CLP Workshop

**The Chair of the HelpNet, Erwin ANNYS** (ECHA) opened the CLP Workshop. He welcomed the representatives of the national helpdesks (NHDs), observers from potential candidate and third countries, and industry who registered for the event (Annex III – List of participants).

The Chair introduced the agenda of the day (Annex I B), informing about the postponement of the topic 'Annex VIII: Relieving toll formulators from notification obligations' proposed by Germany. The agenda was adopted without further comments.

This document summarises the topics discussed during the workshop and the follow-up action points set (Annex II). The summary of the session dedicated to CLP members only will not be published on ECHA's website but shared in S-CIRCABC[17]. The session addressing topics proposed by ECHA and NHDs will be published on ECHA's website[18].

The list of participants is available in Annex III.

## 1. Building competences in the CLP helpdesks [IN CLOSED SESSION]

## 2. Poison centre notifications

### 2.1 Reporting components: focus on Mixture in Mixture (MiM)

Pedro ROSELLÓ VILARROIG and Daniele APE (ECHA) explained how substances and mixtures are reported in a poison centre notification (PCN). The speakers focused on Mixture in Mixture (MiM):

- how mixtures are reported;
- identification of substances and mixtures;
- interchangeable component groups; and
- MiMs identification.

Daniele APE made a live demonstration on how this is done in the IUCLID Cloud. This was a sample of a training that ECHA can provide to NHDs and could help them in the discussion about their training needs.

### Discussion

Some NHDs raised their concern as to which topics NHDs are expected to cover. ECHA clarified that the basis is regulatory questions. The ones on dossier preparation are very close to that topic, but if the NHDs felt unsure, at least they could point the enquirer to the correct piece of support material. That was part of the aim of the handbook.

[17] REACH and CLP Workshops (8-9 June 2021) folders: Path: /CircaBC/echa/HelpNet/Library/02 Steering Group/Workshops/REACH and CLP Workshops (8-9 June 2021)
[18] https://echa.europa.eu/about-us/partners-and-networks/helpnet/2021

## 2.2 Overview of the ECHA helpdesk activities since 2020

Pedro ROSELLÓ VILARROIG gave an overview of the ECHA helpdesk activities, the support material available – including audio-visual material – and the changes in tools implying an update of the support material.

In addition, the speaker talked about an appreciated channel of communication with companies, the LinkedIn group. The presentation then moved to the training needs of the CLP NHDs and two polls were run.

According to the feedback given by the CLP NHDs, nine of them were interested in training on Annex VIII. ECHA pointed out that more had shown interest at some point in time.

There was a preference amongst the NHDs for training sessions through video conferences, to train or keep the NHDs up to date. The topics, in order of most interest were:

- reporting mixtures: overall, MiM;
- dossier creation: standard rules;
- dossier creation: deviations;
- duty holders and supply chain; and
- dossier submission.

### Discussion

A concern, voiced by two NHDs was about the number of questions they would receive, on top of what they are already handling. ECHA pointed out that also the complexity, or lack of it, was a factor to take into account, and that a majority of questions received in ECHA are replied by simply pointing the customer to the right part of the supporting material. Therefore, the increase in actual workload will be more acceptable.

ECHA informed about the status of the revision of Q&A (FAQ) 1727: after receiving comments from the NHDs, the draft was discussed with the Commission. They clarified that the discussion about who was a duty holder would not be considered, as that had been settled by the 'Note to the reader' opening the guidance document. The other input provided was being reflected upon.

One of the NHDs asked about how to handle a query, where a formulator was asking about the validity of the UFI they received from their supplier. The view of ECHA was that neither the NHDs nor ECHA have access to such information, and the enquirer should get a confirmation about its validity from the supplier.

Regarding the status of the FAQ proposal about Article 29(2), the Chair committed to investigate and report back to NHDs in writing.

## 3.1 Update on CLP hot topics

Jérémy PINTE, Sofoklis STRATAKIS and Anna SCHUSTER from the European Commission (DG GROW and DG ENV) gave an update on CLP hot topics, including:

- CLP revision;
- $TiO_2$ classification;
- nail and lash glues; and
- electronic lighters.

Jérémy PINTE opened his presentation about the **CLP revision** by pointing out that the CLP revision was a targeted action under the Chemicals Strategy for Sustainability. The speaker then listed the different areas of the legal text proposed for revision, with some details about the reasons to choose them.

One NHD remarked how ambitious and encouraging the programme was, mentioning that the new hazard classes would have a serious impact on GHS and labelling.

Jérémy PINTE acknowledged the challenge, in particular for endocrine disruptors (EDs), while for PBT substances the way forward seemed clearer, as the criteria are already there, under REACH. When asked about the inclusion of substances in the scope of Article 45, the speaker replied that it is known that other systems already exist. At the end of the impact assessment process, extension of Article 45 to substances may not be the best option.

Regarding $TiO_2$, the Commission noted that having a guidance helping to interpret in a harmonised manner any legal provision is always useful. In this regard, the guidance on $TiO_2$ classification published by the German Helpdesk was generally in line with the Commission's interpretation. The English translation was still under revision and Commission's feedback would be available in a few weeks.

The German correspondent explained that their courtesy translation had been published on the BAuA website and will be replaced by the new one, once the guidance is approved by ECHA and the Commission. He then asked if there had been any comments by stakeholders on the Guidance. The representative of IMA-Europe confirmed that they had sent comments, seeking clarification for $TiO_2$ as an impurity or constituent in substances, as the legal provisions refer to $TiO_2$ as a substance and in mixtures. Sofoklis STRATAKIS confirmed they have received the comments and are discussing them internally.

'Nail and lash glues' was a topic discussed in 2019 and pending since then. Anna SCHUSTER explained that due to the restructuring of DG GROW, the CLP and Cosmetics teams are now in the same unit. The Cosmetics borderline subgroup had met in early 2021 but did not agree on the text proposal. Therefore, the Commission would still be following up on the matter.

'Electronic lighters' was a topic proposed by Ireland in October 2020, starting from HelpEx ID 17306. The original question was: Where an electronic lighter comes under the scope of both the CLP Regulation and the safety standards listed under the General Product Safety Directive, which one takes precedence? While the Commission is in principle always in favour of adopting a pragmatic approach such as the one proposed by HelpNet to avoid the simultaneous application of two pieces of legislation, any chosen approach should be legally sound. Interlinks between the CLP and the General Product Safety Directive (GPSD) need to be carefully assessed.

Anna SCHUSTER informed that the Commission consulted GPSD colleagues in DG JUST and that the services are finalising their analysis. She informed as well that the Commission is currently revising the GPSD. A GPSD aspect to consider is that the GPSD standard "Child safety requirements for lighters" is voluntary, although developed by the European Committee for Standardization (CEN) and published in the Official Journal thus having legal effect. That standard might not be applied by all economic operators while CLP is compulsory for everyone.

Another aspect to consider is the upcoming targeted CLP revision of which its inception impact assessment contains the proposal to assess the possibility to derogate from certain labelling requirements for products in small packaging. Anna SCHUSTER asked if the NHDs could report whether their Member States transposed the voluntary GPSD standard for child safety ("Child safety requirements for lighters").

Post-meeting note: The relevant services concluded that such reporting is not necessary at the moment.

The Irish correspondent said that they understood that they should follow a pragmatic approach and consider that the voluntary standard should apply. Anna SCHUSTER replied that this is a sensible approach, however, from a legal point of view it is tricky to establish that one piece of legislation takes precedence over the other.

The representative of one NHD pointed out that the standards for electronic lighters based on flammability criteria already lead to proper labelling. In their country, they would rather see that appropriate hazard marking is covered by one piece of legislation only. Anna SCHUSTER took note of this conclusion from the NHD that in their country GPSD is considered as adequate and the application of CLP would be superfluous.

### 3.2 Borderlines between CLP and other EU legislations

Outi TUNNELA (ECHA) presented the borderlines between CLP and 12 other relevant pieces of EU legislation. She mentioned that the topic had been a request for training and due to the wide and not so clear limits of the request, she had chosen to present this analysis with the most common pieces of legislation affected.

The presentation gave an overview of the links to CLP for the following: Biocidal Products Regulation, Plant Protection Products Regulation, Detergents Regulation, Medical Devices Regulation, Cosmetic Products Regulation, Toy Safety Directive, Food Contact Materials, Drinking Water Directive, Industrial Emissions Directive, Seveso Directive, Waste Framework Directive, and the Occupational Safety and Health Directive. The main purpose was to emphasise that when addressing questions on mixtures and articles, the existence of possible further product-specific requirements (concerning the chemicals in the product) should not be overlooked.

## Discussion

One participant highlighted the problems of creating unusual classifications in CLP as it has unexpected consequences in a long list of downstream user legislation. Another topic that raised discussion among several NHDs was the difficulty to decide what a new product on the market was, or which legislation should cover them. Normally, it would be easier to decide which legislation would not affect them. An example was nicotine pouches (toxic if swallowed) which are not covered by either tobacco or the medicines legislation, or volcano stones with sensitising aromas. One NHD suggested to rely on CLP if no other specific legislation would fit. Another NHD mentioned that they were investigating the need to develop specific legislation for the case of tobacco pouches, which in any instance would be better to have at EU level.

As some of those questions have been posted in HelpEx, there was a general agreement that they could be collected and raised to the Commission for compilation. Commission could then bring them to CARACAL for discussion and agreement.

One industry observer asked about the mentioned substances in detergents which have been found not adequately assessed for biodegradability. ECHA committed to contact them separately to clarify this point bilaterally.

## Conclusions of the day

**The Chair** gave a short wrap-up of the meeting, thanking participants and presenters for their active and valuable contributions to the meeting. He then informed that the action points would be available shortly in S-CIRCABC.

The HelpNet members and observers were invited to register to ECHA's Safer Chemicals Conference organised on 6 October as a free online event for up to 2 500 external stakeholders. The registration starts on 6 August 2021. The full conference programme is available on the event page: https://echa.europa.eu/fi/-/safer-chemicals-conference

ECHA is experimenting with a new online event platform with multiple interactive areas – including sessions with live Q&A, a virtual exhibition, and speed networking. Participants can move in and out of rooms just like in a physical event. The conference will focus on helping companies become more sustainable and preparing them for the new EU obligations.

The ECHA helpdesks – REST and iTEX – are hosting the stand: 'Get support: meet the helpdesks'. The helpdesks aim to use this event to explain to companies the division of competences between ECHA and NHDs, and novelties (e.g. new contact forms, non-EU customers now also have to contact NHDs, etc).

The Chair also informed about the surveys, the usual satisfaction survey and in addition, a written procedure to be launched to seek NHDs' opinion and final agreement on the new division of competences and ways of working between ECHA and the REACH and CLP NHDs.

HelpNet members and observers were informed that the 16th HelpNet Steering Group meeting and regulatory workshops would take place from 2 to 5 November 2021.

## Annex I A – Agenda

**HelpNet REACH and CLP Workshop**
(Web conference)
**8 June 2021**

### REACH and CLP Workshop

11:00 **Opening by the Chair of HelpNet**

11:15 **1. Division of competences between ECHA and national REACH/CLP helpdesks** [IN CLOSED SESSION]

### REACH Workshop

13:30 **2. Building competences in the REACH helpdesks** [IN CLOSED SESSION]

14:45 **3. REACH topics proposed by national helpdesks and ECHA**

3.1 Update on nanoforms: from registration to evaluation and nanomaterials expert group (Abdelqader Sumrein, Amaia Rodriguez-Ruiz, Frank Le Curieux, ECHA)

3.2 Considerations on the substance definition in a regulatory context (Claus Haas, German Helpdesk)

3.3 Obligations for lead and its compounds in articles (Heinz Bülter, German helpdesk))

3.4 SCIP overview (Helena Järnström, Clara Rueda, ECHA)

16:30 **Conclusions by the Chair**

16:45 **Closing the REACH Workshop**

## Annex I B – Agenda

**HelpNet CLP Workshop**
(Web conference)
**9 June 2021**

### CLP Workshop

11:00 **Opening by the Chair of HelpNet**

11:15 **1. Building competences in the CLP helpdesks** [IN CLOSED SESSION]

13:00 **2. Poison Centre Notification**

2.1 Reporting components: focus on Mixture in Mixture (Pedro Roselló Vilarroig, Daniele Ape, ECHA)

2.2 Overview of the ECHA helpdesk activities since 2020 (Pedro Roselló Vilarroig, ECHA)

Discussion

14:30 **3. CLP topics proposed by national helpdesks and ECHA**

3.1 Update on CLP hot topics (Anna Schuster, Jérémy Pinte, Sofoklis Stratakis, European Commission, DG GROW)

3.2 Borderlines between CLP and other EU legislations (Outi Tunnela, ECHA)

15:45 **Conclusions by the Chair**

16:00 **Closing the REACH Workshop**

# Annex II - Action points

## REACH and CLP Workshop (8 June 2021)

| No. | Action | Agenda item | Who | Status |
|---|---|---|---|---|
| 1. | Interested NHDs to raise awareness regarding SCIP support material (e.g. practical guide on SCIP database) with SCIP colleagues in Member States. | 3.4 | NHDs | Closed |
| 2. | Bilateral follow-up of the question if an NHD can be referred to in questions on SCIP if specifically requested by the customer. | 3.4 | ECHA<br>SE NHD | Closed |

# CLP Workshop (9 June 2021)

| No. | Action | Agenda item | Who | Status |
|---|---|---|---|---|
| 1. | Share the revised text of FAQ 1727 after receiving comments from the Commission. | 2.2 | ECHA | Closed |
| 2. | Update HelpNet on Q&A revision of Article 29(2). | 2.2 | ECHA | Closed |
| 3. | Commission to consider if they need to collect information about the transposition of voluntary EU standard on child safety for e-lighters under GPSD in the Member States. | 3.1 | Commission | Closed |
| 4. | Communicate to HelpNet members the outcome of the final version of the TiO2 document after the feedback received from the European Commission. | 3.1 | ECHA | Closed |
| 5. | Bilateral follow up on ingredients in detergents not assessed for biodegradability. | 3.2 | ECHA<br>A.I.S.E. | Closed |

# Annex III - List of participants

## MB member

| | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| Austria | Paul KRAJNIK | x | |

## HelpNet members

| Country | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| Austria | Barbara WETZER | x | x |
| | Erich NEUWIRTH | x | x |
| Belgium | Daphné HOYAUX | x | x |
| Croatia | Romana GRIZELJ | x | x |
| | Silva KAJIĆ | | x |
| | Zdravko LOVRIĆ | x | |
| | Irena Zorica JEŽIĆ VIDOVIĆ | x | x |
| Cyprus | Maria ORPHANOU | x | x |
| | Maria PALEOMILITOU | x | x |
| Czech Republic | Jarmila SLÁDKOVÁ | x | x |
| Denmark | Ditte PALUDAN | x | x |
| | Maria THESTRUP JENSEN | x | |
| Estonia | Anna AMELKINA | x | |
| | Aigi LAHE | x | x |
| Finland | Tarja KARLEMO | x | x |
| | Pauli KÄRKKÄINEN | | x |
| | Sari TUHKUNEN | x | |
| France | Nathalie HAYAUD | x | x |
| | Gaëlle DUFFORT | x | x |
| | Stephanie COPIN | x | x |
| Germany | Claus HAAS | x | |
| | Heinz BÜLTER | x | |
| | Nicolaj HEUER | | x |
| Greece | Elli Maria APERGI | x | |

| Country | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| Hungary | Nikoletta MAROSVÖLGYI | x | x |
| Iceland | Bergdís Björk BÆRINGSDÓTTIR | x | |
| | Fifa KONRADSDOTTIR | x | x |
| Ireland | Majella COSGRAVE | x | x |
| Italy | Sonia D'ILIO | x | x |
| | Francesca GIANNOTTI | x | |
| | Francesca CARFÌ | x | x |
| | Maria ALESSANDRELLI | x | x |
| | Sabrina MORO IACOPINI | x | |
| Latvia | Elīna LAZDEKALNE | x | x |
| Lithuania | Agnė JANONYTE | x | x |
| | Beata VOLUJEVIČ | x | x |
| | Jurgita BALČIŪNIENĖ | x | x |
| | Otilija ŠPŪRIENĖ | x | x |
| Luxembourg | Laurène CHOCHOIS | x | x |
| | Oona FREUDENTHAL | x | |
| Malta | Nathanael ELLUL | | x |
| Netherlands | Femke AFFOURTIT | | x |
| | Peter VAN IERSEL | x | x |
| Norway | Cecile BLOM | x | x |
| | Bodil FAARLUND | x | x |
| | Ann Kristin LARSEN | x | x |
| | Abdulqadir SULEIMAN | x | x |
| Poland | Krzysztof DOMAŃSKI | x | x |
| | Monika WASIAK-GROMEK | x | x |
| Portugal | Fátima de Maria ARAÚJO | x | x |
| | Isabel LAGINHA | x | x |
| Romania | Nicoleta CAROLE | x | x |
| Slovakia | Martina KOKAVCOVA | x | x |
| | Dasa PAULIKOVA | x | x |
| | Lucia MURANIOVA | x | x |
| Slovenia | Anja MENARD SRPČIČ | x | |
| | Simona FAJFAR | x | x |
| Spain | Elena Maria SANCHEZ DIAZ | x | x |

| Country | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| | Laura ZAMORA NAVAS | x | x |
| Sweden | Karin ALKELL | x | |
| Sweden | Helena DORFH | x | |
| | Jonas FALCK | x | x |
| | Susanna NORRTHON RISBERG | x | x |
| | Jenny VIRDARSON | x | x |
| | Ingrid WIRÉN | x | |

**European Commission**

| DG | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| DG GROW | Anna SCHUSTER | | x |
| DG GROW | Jérémy PINTE | | x |
| DG ENV | Sofoklis STRATAKIS | | x |
| DG GROW | Riccardo ZORGNO | x | |

**Observers from candidate countries**

| Country | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| Montenegro | Nevena BOGAVAC | x | x |
| | Tatjana MUJICIC | x | x |
| | Ilija GOJOVIC | x | x |
| Turkey | Isil ORHAN | x | x |

**Observers from third country**

| Country | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| Switzerland | Markus HOFMANN | | x |

**Observers from industry**

| Organisation | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| A.I.S.E. | Jan ROBINSON | x | x |
| Cefic | Liisi DE BACKER | | x |
| CEPE | Kristien DE PAUW | x | x |
| Fecc | Simina DREVE | x | |
| IMA Europe | Roger DOOME | x | x |
| ORO | Kevin HOBAN | x | |

## ECHA staff

| Unit | Name, surname | REACH and CLP Workshop | CLP Workshop |
|---|---|---|---|
| A0 | Jukka MALM | x | |
| | Kirsi PITKANEN | x | |
| A2 | Anisa KASARUHO | x | x |
| | Carmen KLAUSBRUCKNER | x | x |
| | Christina LOUKOU | x | x |
| | Elena BIGI | x | x |
| | Erwin ANNYS | x | x |
| | Helena JÄRNSTRÖM | x | x |
| | Malgorzata SZKLAREK | x | x |
| | Martina FORTE | x | x |
| | Pedro ROSELLÓ VILLAROIG | x | x |
| | Peter SIMCIC | x | x |
| | Roxana BROASCA | x | x |
| | Viorica NAGHY | x | x |
| A3 | Clara RUEDA | x | |
| | Claudia RIMONDO | x | |
| | Daniele APE | | x |
| | Heidi RASIKARI | | x |
| | Javier SANCHEZ SAEZ | | x |
| | Rémi LEFEVRE | x | |
| | Tiago PEDROSA | x | x |
| A4 | Abdelqader SUMREIN | x | |
| B1 | Michal SKOWRON | x | |
| B4 | Outi TUNNELA | | x |
| | Telmo Jorge VIEIRA PRAZERES | x | |
| C1 | Ari KARJALAINEN | x | |
| C2 | Amaia RODRIGUEZ-RUIZ | | x |

| | | | |
|---|---|---|---|
| C4 | Frank LE CURIEUX | x | |
| D3 | Augusto DI BASTIANO | x | |
| E1 | Gabriela CSEH | x | |
| | Jenny HOLMQVIST | x | |
| | Jenni HOLSTI | x | x |
| R3 | Hilde-Renate ERIKSEN | x | X |
| R3 | Marko POPOVIC | x | x |