

# 2022 Report of National and ECHA Helpdesks Activities: Overview

2 May 2023



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### List of acronyms

ADR Transport of Dangerous Goods by Road

BPR Biocidal Products Regulation (EU) 528/2012

Chesar Chemical Safety Assessment and Reporting Tool

CLP CLP Regulation (EC) 1272/2008 eCA Evaluating competent authority

ECHA Tool that allows EU-based companies to submit information on chemicals Submission regulated by several legislations, including poison centre and SCIP

portal notifications and EFSA applications

EEA European Economic Area FAQ Frequently asked questions

Forum Forum for Exchange of Information on Enforcement

FTE Full time equivalent

GMOs Genetically modified organisms

HelpEx Tool to communicate and discuss questions among the members of HelpNet HelpNet BPR, CLP and REACH Helpdesk Network, consisting of representatives from

the national helpdesks of the 27 EU Member States, as well as Iceland,

Liechtenstein and Norway, ECHA and the European Commission

HelpNet Service within the Support and Enforcement Unit of ECHA responsible for

Secretariat the coordination of HelpNet activities

IUCLID International Uniform Chemical Information Database, ECHA's central

repository of chemical data

NHD National helpdesk
OR Only representative
PCN Poison centre notification

PIC Prior Informed Consent (Regulation)

POP Persistent organic pollutants
PPP Plant protection products
UFI Unique formula identifier
O&A Ouestion and answer

REACH Regulation (EC) 1907/2006

REACH-IT Central IT system to submit data under the REACH and CLP regulations
RoHS Directive on the restriction of the use of certain hazardous substances in

electrical and electronic equipment

R4BP Register for Biocidal Products

SCIP SCIP is the database for information on substances of concern in articles as

such or in complex objects (products) established under the Waste

Framework Directive (WFD)

SDS Safety data sheet

SME Small and medium-sized enterprise SVHC Substance of very high concern

UA Union authorisation

VOC Volatile organic compounds

### Foreword by the Chair of the HelpNet



While the spring is progressing slowly in Finland, other parts of Europe are already suffering from forest fires, extreme dryness, and extreme unseasonal high temperatures. The very high ambitions set out in the Green Deal of the European Commission led by Ursula von der Leyen are absolutely essential to keep our continent and our planet as an attractive place for our children and next generations.

In the Chemicals Strategy for Sustainability much is happening. The CLP Delegated Regulation has been published and entered into force introducing new hazard classes that will help to protect next generations from substances having a negative impact on health and environment. The discussions on the

revision of the core text of the CLP Regulation is ongoing in the Council and the European Parliament. An improved protection for internet sales and better clarification of the bridging principles are only some of the many changes proposed by the Commission. The REACH revision, officially scheduled for the end of 2023, is also progressing.

The combination of changes will clearly need enhanced support to companies in the coming years with an influence on the workload of the national and ECHA Helpdesks. Last year we received more than 40 000 questions handled by our national helpdesks and 9 500 for the ECHA helpdesks. With all the upcoming changes we can only expect more questions to continue coming in. As the Chair of the HelpNet, I can assure that we are already reflecting on how to handle this in the best way, using the success experiences from the past and leaving room for more innovative approaches to support companies to be or become compliant with the legislations that we have in place in the European Union. We really need to think about how we can deliver the best service, not being limited to the bigger companies but also thinking about and exploring the best ways to interact with and inform SMEs which represent 99% of all businesses in the European Union.

Another challenge will be the new tasks that are coming to ECHA. We are steadily moving away from a REACH centred Agency towards a broader chemicals legislation centred Agency which will result in many more SMEs and other stakeholders being confronted with our activities. Again, innovative ideas will be needed to move in that direction.

Unfortunately, Russia's unprovoked military aggression against Ukraine continues. ECHA is working closely together with the Commission on the sanctions that are in place and will update stakeholders on the progress made in due course.

I hope you enjoy reading this report.

Erwin Annys Chair of the HelpNet

#### 1. Introduction

Each year, the national BPR, CLP and REACH helpdesks report to ECHA on their activities, workload, internal organisation, and other topics of interest. This report summarises the activities of the national helpdesks (hereinafter NHDs) from 1 January to 31 December 2022.

The HelpNet Secretariat collected the information over the period December 2022 to February 2023 via a web-based survey. The survey was open to the NHDs of the 30 EU/EEA countries and observers from three EU candidate countries, as well as a third-country observer of the HelpNet (for BPR and CLP). Overall, the responses provided reflect the activities of the BPR, CLP and REACH helpdesks¹ across **34 countries**. In addition, this report includes a section dedicated to the ECHA Helpdesks activities.

In 2022, ECHA and the national helpdesks continued to foster and further develop their cooperation through the HelpNet network, to achieve a common understanding on the legal requirements under the BPR, CLP and REACH regulations and the provision of consistent and harmonised advice to stakeholders. The main activities and new initiatives of the network are presented in a dedicated section of this report.

#### 2. Overview of enquiries received by national helpdesks

### 2.1 Total number of enquiries received and overall trends

In 2022, NHDs received 42 762 enquiries from their customers on the BPR, CLP and REACH regulations<sup>2</sup>, of which 56% were related to BPR, 21% to CLP, and 23% to REACH, as presented in Figure 1 - Enquiries received by NHDs in 2022, split by regulation.

The number of enquiries reported by NHDs defines how many times a customer contacted the helpdesk by various means of contact (contact forms, e-mails, phone calls, etc.). Sometimes, one e-mail, or phone call may be counted as one enquiry although the customer may have asked several questions. The total number of BPR, CLP and REACH enquiries<sup>3</sup> received by NHDs (42 762) in 2022 decreased by about 22% compared to 2021 (55 045). It however returned to a level comparable to the workload of the years 2017-2019.

 $<sup>^{\</sup>mathrm{1}}$  58 respondents to the survey representing 29 BPR, 31 CLP and 32 REACH NHDs.

<sup>&</sup>lt;sup>2</sup> The information is based on figures reported by the NHDs. Trends presented in this report are indicative as they rely on data provided by the reporting NHDs only.

<sup>&</sup>lt;sup>3</sup> For more information on 2021 statistics, see '2021 Report on National Helpdesk Activities: Overview' at: <a href="https://echa.europa.eu/about-us/partners-and-networks/helpnet/2021">https://echa.europa.eu/about-us/partners-and-networks/helpnet/2021</a>

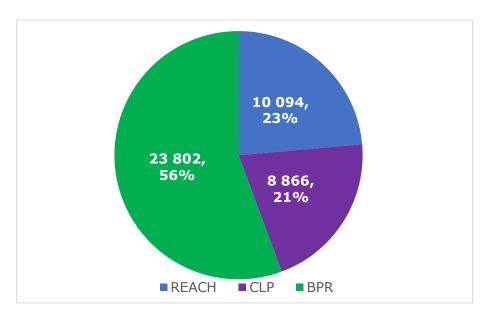


Figure 1: Enquiries received by NHDs in 2022, split by regulation

#### **Main observations**

BPR remains the regulation with the highest number of questions replied to by NHDs, as it has been since 2018, followed by REACH and CLP. This continues to differentiate NHDs from ECHA, for which the number of REACH questions has been the highest in the last five years. Although the need for BPR NHD support was no longer linked to enquiries related to the pandemic, a shift was noticed from COVID-19 related queries to more general ones on products placed on the market under transitional measures and national authorisations. The number of REACH enquiries slightly decreased in comparison with the previous four years. A drop in the number of CLP related enquiries was also noticed.

Overall, the decline in the number of enquiries could be interpreted as a sign of a better understanding of the various pieces of chemical legislation among duty holders. Besides, 2022 was a year without any new specific regulatory deadline or compliance date under REACH, including SCIP notification, or CLP. Finally, some NHDs noted that their website was visited more often in 2022 and considered that companies and stakeholders found the reply to their questions directly online thanks to the published support material.

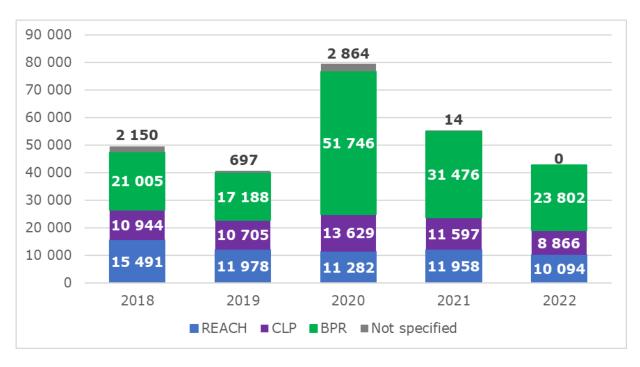


Figure 2: Total number of enquiries received by NHD from 2018 to 2023

### 2.2 Hot topics of regulatory enquiries

National helpdesks (NHDs) reported on the hot topic questions raised by their customers. The five most frequent topics reported for each regulation are shown in Figure 3: Overview of the BPR, CLP and REACH hot topics received by NHDs in 2022.

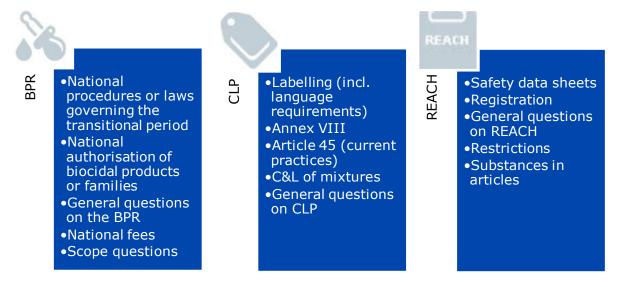


Figure 3: Overview of the BPR, CLP and REACH hot topics received by NHDs in 2022

#### 2.3 BPR enquiries received by national helpdesks

In 2022, the total number of BPR enquiries received by 29 NHDs was 23 802, representing 56% of all received enquiries. The percentage remains almost unchanged in comparison with the previous year. This makes BPR the most popular regulation once again. However, in

absolute number, the BPR enquiries decreased by 7 674 from 2021 to 2022, which corresponds to a decrease of 24,4%.

Six of the BPR helpdesks received above 1 000 questions in 2022, while there were ten receiving such a number in 2021. One of them received up to 6 400 enquiries in 2022. For comparison, the highest number of enquiries received by a NHD was 9 000 in 2021.

In 2022, the NHDs reported having received significantly fewer enquiries linked to the COVID-19 pandemic. The high number of BPR enquiries replied to in 2021 was directly related to the pandemic years and the urgent demand for placing disinfectants on the market. The trend is now returning to normal mode, with a transition from specific COVID-19 questions to more general queries on national procedures governing the transitional period, national authorisations and national fees. As presented in the below table, for BPR, apart from the lack of COVID-19 questions, there is no significant change observed in the hot topics of enquiries.

### **BPR** hot topics

Table 1: Hot topics concerning the Biocidal Products Regulation in 2022 and 2021

2022	2021	
National procedures/laws governing the transitional period	1	National procedures/laws governing the transitional period
National authorisation of biocidal products or families	2	National authorisation of biocidal products or families
General questions on the BPR	3	National fees
National fees	4	General questions on the BPR
Scope questions	5	COVID-19
Active substance approval (or renewals)	6	Scope questions
In situ generation of active substances	7	In situ generation of active substances
Treated articles	8	Active substance approval (or renewal of active substance approval)
Article 95 listing and enforcement	9	Substance identity
Re-definition of substances	10	Re-definition of substances

As expected, in 2022, the top four positions continue to be occupied by topics that fall within the remit of national authorities. Other hot topics that remain in the list, although in a slightly different order than in 2021, include 'Active substance approval' and 'Scope questions'. The topic of 'Enforcement', which lies with national authorities, did not rank highly, suggesting that NHDs do not get many questions on enforcement related matters. As expected, 'Article 95 listing and enforcement' also ranked low given that the topic falls within ECHA's remit, while the enforcement of compliance with Article 95 provisions lies with the national enforcement authorities. As in 2021, 'Re-definition of substances' remains in the last position.

In addition to the hot topics highlighted in the above table, some NHDs reported having received many enquiries on the labelling of biocidal products. This may be a consequence of the enforcement activities targeting biocides labels. Queries on in situ generated substances and products placed on the market under Article 93 (e.g., 'ozone generated from oxygen', or 'free radicals generated from ambient air and water'), and requests for acting as evaluating Competent Authority for union authorisation applications were also mentioned.

### 2.4 CLP enquiries received by national helpdesks

The total number of CLP enquiries (8 866) represented 21 % of all received enquiries, with an overall decrease of 2 731 enquiries. However, the share of CLP enquiries out of all enquiries received remained similar to the previous years. Out of all CLP helpdesks, two received more than 1 000 questions in 2022 in comparison with three who did so in 2021 and 2020. The highest number of queries received by one national helpdesk was 1 500 enquiries in 2022, compared to 2 350 the previous year. These elements support the observation that, overall, companies have contacted their NHDs less.

The decrease in CLP enquiries was possibly due to the absence of a CLP specific deadline or PCN compliance date in 2022. Similar to the BPR related enquiries, some NHDs also mentioned that some of the questions previously referred to the helpdesk were probably addressed by the local enforcement authorities. The number of questions related to Poison Centre Notification (PCN) duties decreased, as duty holders became more familiar with the PCN related requirements. In addition, the ECHA Poison Centres website<sup>4</sup> was translated into all EU official languages, as were both the *Guidance on Annex VIII to CLP* and the *PCN practical guide*. Some NHDs reported no significant change in the overall number of questions, but rather on certain topics. As presented in the below table, there were few differences between the top ten topics in 2022 compared to 2021.

### **CLP** hot topics

Table 2: Hot topics concerning the CLP Regulation in 2022 and 2021

2022		2021
Labelling (including language requirements)		Annex VIII
Annex VIII	2	Labelling (including language requirements)
Article 45 (current practices)	3	Article 45 (current practices)
Classification and labelling of mixtures	4	Classification and labelling of mixtures
General questions on CLP <sup>5</sup>	5	General questions on CLP
Packaging	6	Harmonised classification/Annex VI
Harmonised classification/Annex VI	7	Related EU chemicals legislation
Classification of substances	8	Packaging
Related EU chemicals legislation <sup>6</sup>	9	Classification of substances
Classification and labelling of TiO2 <sup>7</sup>	10	Use of alternative chemical name

'Labelling', 'Annex VIII', 'C&L of mixtures' and 'Article 45' were still occupying the first four positions, even though there was a change of order. 'General questions of CLP' remained in the

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<sup>&</sup>lt;sup>4</sup> <a href="https://poisoncentres.echa.europa.eu/">https://poisoncentres.echa.europa.eu/</a>

<sup>&</sup>lt;sup>5</sup> Questions on scope and exemptions, as well as on roles and obligations under CLP

<sup>&</sup>lt;sup>6</sup> Questions on other EU chemicals legislations related/at the borderline/overlapping or parallel with CLP: Classification of substances

<sup>&</sup>lt;sup>7</sup> Titanium dioxide.

fifth position, as seen in 2021 and 2020. 'Related EU chemicals legislation' dropped to ninth position, regardless of a growing interest in tobacco-like products, as shown by questions and agenda points of the HelpNet events over the last two years. The topic of 'Packaging', on the contrary, rose two positions. 'Classification and labelling of TiO2' was introduced due to the new classification mandated by a Commission Regulation. It may be assumed that the publication of the Guide<sup>8</sup> prevented this topic from becoming more frequent. However, it may become relevant again following the General Court<sup>9</sup> ruling that annulled the related Commission Regulation, and the following appeals lodged against it.

Going into further detail, NHDs highlighted receiving questions on the specific topics of online sales, refilling, labelling related to fold-out labels, digital labels and use of QR-codes to provide multi-lingual information. Questions from candle makers on their obligations under Annex VIII, and specific questions related to the creation and use of the UFI were also mentioned. Finally, NHDs reported receiving questions on the C&L inventory and notifications, on enforcement and compliance, and on SDS.

### 2.5 REACH enquiries received by national helpdesks

The total number of REACH enquiries (10 094) represented 23 % of all received enquiries. This percentage increased slightly in comparison with the previous year. However, in absolute numbers, the REACH enquiries decreased by 1 864. Out of all REACH helpdesks, three received more than 1 000 questions in 2022, as seen in 2021 and 2020. The highest number of queries received by one national helpdesk was 1 428 enquiries in 2022, compared to 1 657 in 2021.

Some NHDs observed a slight decrease in the number of questions they received in 2022, in particular for general enquiries and questions related to authorisation and SCIP obligations. As for CLP enquiries, this decrease might be related to the absence of specific regulatory deadlines such as REACH registration or SCIP notification deadlines.

It was also noted that some NHDs have developed further support material on their websites, which could go some way to explain a decrease in the numbers of enquiries. On the other hand, other NHDs noted an increase in the number of questions they received for enquiries related to registration, authorisation, restrictions and substances in articles.

In general, it was noted that the number of questions received decreased to pre-COVID levels, but that the enquiries received were generally of a more complex nature.

### **REACH hot topics**

Table 3: Hot topics concerning the REACH Regulation in 2022 and 2021

2022		2021
Safety data sheets	1	Safety data sheets
Registration <sup>10</sup>	2	General questions on REACH
General questions on REACH <sup>11</sup>	3	Registration

<sup>&</sup>lt;sup>8</sup> https://echa.europa.eu/-/new-guide-available-on-classifying-and-labelling-titanium-dioxide

<sup>&</sup>lt;sup>9</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62020TJ0279

<sup>&</sup>lt;sup>10</sup> Questions on registration obligation, dossier preparation and update, tonnage requirements, information requirements.

<sup>&</sup>lt;sup>11</sup> Questions on scope and exemptions (e.g., Annex V) as well as on roles and obligations (such as importer and only representative roles) under REACH.

Restrictions		Substances in articles	
Substances in articles		Restrictions	
Authorisation		SCIP and Article 33 obligations	
SCIP and Article 33 obligations		Authorisation	
Related EU chemicals legislation <sup>12</sup>		Related EU chemicals legislation	
Data sharing and joint submission		Data sharing and joint submission	
Substance identity		Substance identity	

For REACH, the observed trends of the hot topics in the last three years are very similar. The first three topics, namely 'Safety Data Sheets', 'Registration' and 'General questions on REACH' remained the same as in 2021, as did the first five too, although their ranking changed slightly. Enquiries concerning 'Restrictions', 'Substances in articles', 'SCIP and Article 33 obligations', 'Authorisation', 'Related EU chemicals legislation' and 'Authorisation' remain as high as in 2021, occupying almost the same positions since 2020. 'Data sharing and joint submission' and 'Substance Identity' appeared in ninth and tenth position. Some NHDs mentioned receiving various enquiries on waste and recycling, the candidate list, as well as enquiries on topics overlapping with other regulations such as SEVESO, Market surveillance, POPs, Mercury and VOCs.

The majority of NHDs did not report overall significant change in the most frequently asked topics, although one indicated that in their case there was a noticeable decrease in the topic 'Authorisation' and an increase for 'Substances in articles obligations' related questions. In general, questions about imports and articles' import were high. Two NHDs indicated a noticeable increase of questions on restrictions, likely caused by the adoption of new restrictions. Another NHD noted an increase in questions related to recycling and end-of-waste status. Three NHDs highlighted the important number of SDS and e-SDS related questions, whilst another NHD indicated expecting an increase in this topic in 2023. Finally, NHDs expect an increase of questions on restrictions in 2023, on existing restrictions (e.g., diisocyanates, lead qunshot) or proposed restrictions (e.g., PFAS).

### 2.6 Support provided by national helpdesks on other EU regulations

In 2022, NHDs from 22 countries reported that they replied to 7 738 enquiries on EU chemicals legislation other than BPR, CLP and REACH. Among those, five NHDs replied to more than 500 enquiries on such topics.

As presented in Figure 4: Number of NHDs providing support on other pieces of EU regulations below, the top five most common pieces of legislation triggering enquiries were the Waste Framework Directive (WFD), Persistent Organic Pollutants (POPs), Prior Informed Consent (PIC), Detergents and Cleaning Products Regulation, and Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive (RoHS).

<sup>&</sup>lt;sup>12</sup> Questions on other EU chemicals legislations related, at the borderline, overlapping or parallel with REACH, such as Medicinal Products Regulation, PIC, Cosmetic, Seveso Directive, or Water Directive.

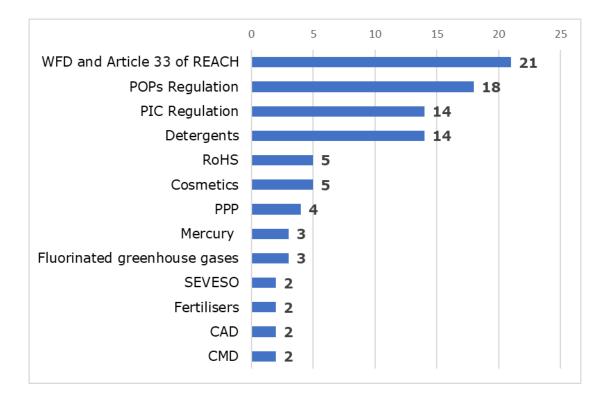


Figure 4: Number of NHDs providing support on other pieces of EU regulations

### 3. National helpdesks and customer support

### 3.1 Communication channels, service response time, and resources

#### **Communication channels**

In 2022, almost 40 000 enquiries received by NHDs were addressed to them via contact forms, e-mails, and phone calls. Another 3 000 were collected via other means of communication, e.g., during meetings. Three NHDs mentioned that they do not keep statistics on enquiries received by various channels, but confirmed the trends shown in Figure 5: Communication channels used by customers to contact NHDs.

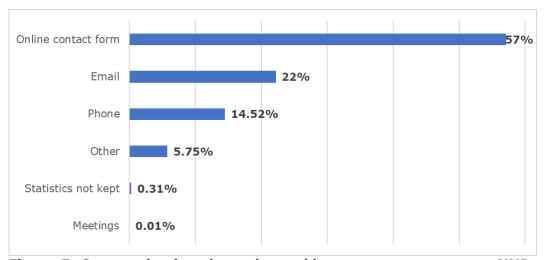


Figure 5: Communication channels used by customers to contact NHDs

#### Service response time

The average response time reported by NHDs was determined mostly by the allocated resources their organisation devotes to their helpdesk activities, and by the complexity of the questions received. For staff involved in the activities of both the helpdesk and the competent authority, prioritisation of tasks had an impact on the time required to answer questions.

In general, NHDs aimed at answering enquiries as soon as possible, respecting the deadlines required by national laws or internal procedures. While simple questions could be replied within a few days, the most complex questions may be replied to within a timeframe of between 30 to 50 days, e.g., when those enquiries required further internal or external consultation. Based on the information provided by the reporting NHDs, the minimum and maximum response timeframe for different types of questions received in 2022 is shown in **Table 4**.

	Response time			
Complexity of enquiry	Minimum	Maximum		
Simple	0.5	7		
Moderate	1	30		
Complex	3	50		

### **Resources**

In 2022, from all NHDs that provided information on their resources, 22 NHDs (eight REACH, nine CLP and five BPR) faced resource cuts while continuing to provide high quality support and harmonised answers to queries. Typical reasons for the cuts included staff leaving the organisation and not being replaced, or resource allocated to other tasks due to fewer queries being received, and prioritisation. In terms of full-time equivalents (FTEs), in total NHDs reported between 0.1 and 10 FTEs allocated to helpdesk activities.

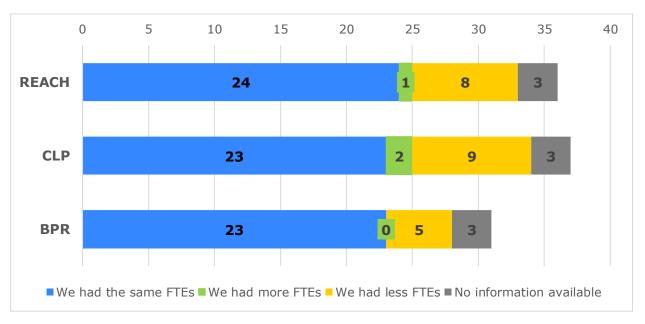


Figure 6: Resources available to provide helpdesk advice in 2022 compared to 2021

### 3.2 Ways to support companies

In 2022, NHDs interacted with their customers mostly through online events, social media and phone calls. In the survey, they shared their experiences on what they found to be the most useful ways to support their customers:

- Participating in events, seminars, workshops, training sessions, teleconferences, and phone calls. Remote and hybrid events enabled reaching more stakeholders.
- Being available for their customers every day for set hours on the phone.
- Running social media campaigns, and publishing newsletters and factsheets.
- Keeping the information on their website up-to-date, publishing short guidance documents and creating new contact forms.
- Developing standard email replies to the most common enquiries received.

NHDs also found it efficient to increase their cooperation with colleagues involved in other bodies (e.g., CARACAL), enforcement, or other departments (e.g., legal services), as well as local competent authorities or from neighbouring countries. They also found enhancing the cooperation with ECHA very useful, by discussing difficult topics, using ECHA support material and the Q&A web section, and working within the HelpEx platform.

#### 3.3 Events

#### **Events organised in 2022**

In 2022, NHDs organised more face-to-face and hybrid meetings compared to the previous year, when remote meetings were then the norm. For BPR, the most common topics tackled at those events included the basic obligations for biocidal products, and information material related to Article 95 listing and treated articles (textile, clothing, garment industry). For REACH and CLP, the events covered topics such as Annex VIII duties, the basics of CLP, the basics of REACH, quality of safety data sheets, and substance identity. Workshops and webinars were also organised on tattoo-ink restriction, diisocyanate restriction, per- and polyfluorinated substances, supplying articles containing substances of very high concern, the SCIP database and on how to support small and medium enterprises.

More specific events addressed issues linked to environmental protection related to substitution, essential oils, cosmetics and household chemicals, chemical products in food markets, and other pieces of regulation such as Persistent Organic Pollutants, Prior Informed Consent, Detergents and Cleaning Products Regulation. Some events were specifically targeted to SMEs, inspectors, consultants, universities, professional associations, or NGOs.

#### **Events planned for 2023**

The NHDs also reported on events and communication activities that they plan to organise in 2023. Chemicals Strategy for Sustainability, the REACH and CLP revisions were topics on the agenda of several NHDs. In addition, the following events are planned, some being similar to the ones already offered in 2022:

- BPR information session on the basics of the BPR, events on Article 95 obligation, on 'in situ' generated active substances, and on BPR enforcement.
- Information session on the basics of CLP and on Annex VIII duties, events on advertisement under CLP (Article 48), and on new requirements for SDS following the application date of Regulation (EU) 2020/878.
- REACH information session on the basics of REACH, events on SCIP database, authorisation, and restrictions (e.g., PFAS restrictions, prohibition of lead in gunshot and wetlands, microplastics).

More specific topics covered by upcoming events include electronic products and leaded glass windows.

### 4. ECHA Helpdesk activities

### 4.1 Regulatory enquiries received by ECHA and hot topics

In 2022, the regulatory helpdesk received 4 394<sup>13</sup> regulatory enquiries, of which 2 772 on REACH, 780 on CLP and 774 on BPR. Additionally, replies were made to 21 enquiries on POPs and to 8 enquiries related to the Drinking Water Directive.

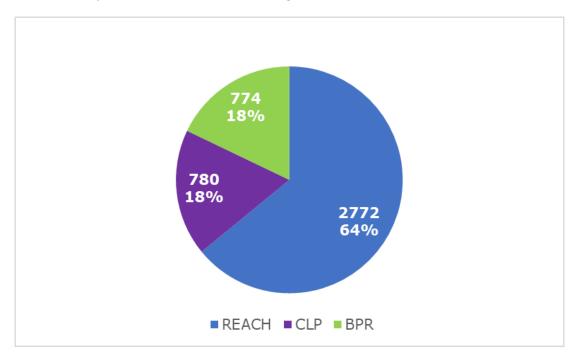


Figure 7: Regulatory enquiries received by ECHA in 2022 for REACH, CLP and BPR14

In comparison with 2021, the total number of regulatory BPR, CLP and REACH enquiries received by ECHA Helpdesk in 2022 decreased by 16%. While the number of REACH questions remained stable compared to the previous year, CLP-related enquiries dropped by 46% while those for BPR dropped by 21%. The latter however remains within the norm of pre-covid numbers. With reference to the reduction of CLP questions received by ECHA, this may be due to the fact that customers now go directly to their NHDs as the first contact point for CLP or, as noted by NHDs, to the lack of regulatory deadlines and increase of support material on the ECHA and NHDs' websites. In addition, the obligations under Annex XVIII became 'business as usual' for operators in its second year of application.

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<sup>&</sup>lt;sup>13</sup> The present numbers do not cover the PCN-related questions replied to in the LinkedIn group.

<sup>&</sup>lt;sup>14</sup> This chart does not show 68 additional regulatory enquiries received on miscellaneous topics.

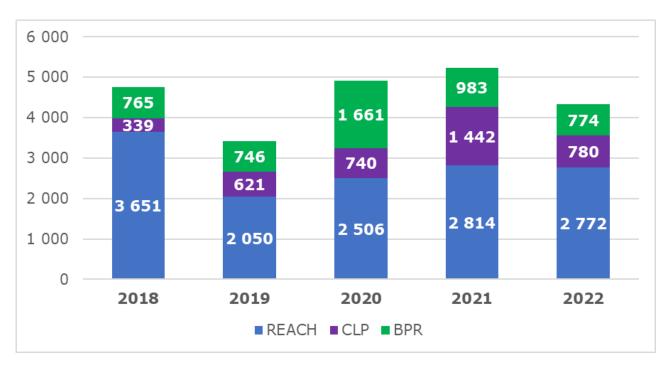


Figure 8: Total number of regulatory enquiries received by ECHA 2017-2022

The hot topics of regulatory enquiries received by ECHA are presented below for each regulation.

#### Hot topics of regulatory enquiries

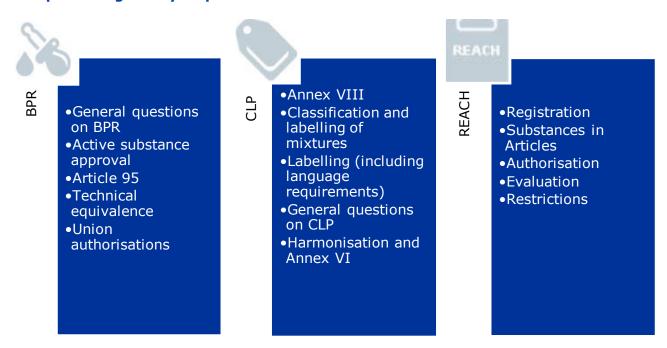


Figure 9: Overview of the BPR, CLP and REACH hot topics received by ECHA in 2022

### 4.2 BPR enquiries received by ECHA

In 2022, the ECHA Helpdesk replied to 774 BPR questions of which only 1% were related to Covid-19. This represents a decline of about 21% compared to 2021. The number of queries in 2022 is comparable with the number of questions replied to in the years 2018-2019, before the pandemic, which seems to indicate a return to normality.

### **BPR** hot topics

General questions on the BPR regulation, followed by questions on active substance approval and Article 95 remained the most popular ones, as was already the case in 2021. However, a drop in the number of questions in all those three categories, mirroring the general trend, has been observed. The number of questions on technical equivalence has remained stable, while enquires on union authorisations have doubled. As regards to general questions on the BPR regulation, the number of questions amounts to 39% of the total of enquiries received. Those enquiries mainly covered the obligations for placing biocidal products on the market. Customers were especially interested in knowing whether their products benefited from transitional measures under Article 89, e.g., for cases where products contained more than one active substance/product type (PT) combination, one of which was already approved.

Additionally, questions on active substance approval represented 14% of the total number of BPR questions. The approval date of ozone generated from oxygen/PT2, PT4, PT5, PT11 and ADBAC/BKC (C12-16)/PT1, PT2 were in the spotlight. Finally, the approval of active chlorine species i.e., Active chlorine generated from sodium chloride by electrolysis, Active chlorine released from sodium hypochlorite and Active chlorine released from hypochlorous acid, triggered a lot of interest not only in relation to the deadline for product authorisation applications, but also in relation to the Article 95 obligation (see below) and technical equivalence. Specific questions related to the approval of active chlorine species represented 7% of the total BPR questions.

Questions related to Article 95 obligation, the third most popular topic, made 9% of the total BPR queries. Customers needed general clarifications in relation to the approval of active chlorine species and more specific explanations for the use of devices for the production of releasers placed on the market as a final product in bottles.

For enquiries related to union authorisations (UA), which represented 6% of the BPR questions, ECHA received a high number of questions from prospective applicants who had encountered difficulties in finding an evaluating Competent Authority (eCA) for their upcoming UA submission. The same issue appeared also in the context of national authorisations. In replying to these questions, ECHA has highlighted that the decision to accept the role of the eCA lies with the national authorities.

### 4.3 CLP enquiries received by ECHA

In 2022 ECHA received a total of 780 questions on CLP. This is a significant drop of 46% compared to the 1 442 received in 2021. Looking at the numbers and topics of last year, and the way ECHA worked with the NHDs this appears linked to the fact that, contrary to 2021, poison centre notification (PCN) duties are nowadays becoming more of a daily business amongst companies who therefore require less support in the second year of application. The decrease in PCN questions is reported as 60%, although it remains the most frequent topic. Moreover, 2022 was the first full year of redirection of questions to NHDs, as agreed with them in 2021 and based on the division of competences outlined on the ECHA website.

It may be reasonable to expect an increase of CLP questions in 2023 and beginning of 2024, as 1 January 2024 is the second application date for the PCN duties and as the new CLP delegated act will come into force already in April 2023.

#### **CLP** hot topics

The most frequent topic for enquiries was again Annex VIII in all its aspects. The number of questions amounts to 43% of the total of CLP questions received. Companies asked for support on many aspects of their duties under Annex VIII. Non-EU distributors, facing pressure from both EU suppliers and customers expecting them to comply with the PCN duties, contacted ECHA to ask how to notify to poison centres. Companies also asked whether certain modifications of their product required an update or a correction of their PCN notification. In addition, the option to disable a notification in the PCN portal was made available during last year and companies contacted ECHA to understand when they could benefit from it.

The next three topics represented another 43% of the CLP questions: classification matters, labelling and safety data sheets (SDS), and general questions about the regulation. Each of them got a very similar share, between 15% and 14%. Regarding classification, questions related mostly to mixture classification. Labelling questions typically touched upon very practical issues such as the placing of the label, font size, and inclusion of several languages on the label. Questions on SDS ranged from the actual need to provide an SDS to how and where to report certain hazards or exposure limits, in particular for substances which may not contribute to the classification of the mixture. General questions about the regulation covered questions related to its scope. At a noticeably lower level (6% of all questions), ECHA received questions about harmonised classification (CLH) and alternative chemicals name under REACH Article 24.

Finally, a sensitive topic in 2021 was the classification of titanium dioxide (TiO<sub>2</sub>) until the guide<sup>15</sup> was published, as also indicated under section 2.4. In 2022, ECHA received questions just after the Court ruling annulling the delegated Commission Regulation on the harmonised classification. It remains to be seen if, in 2023, following the appeals from France and the Commission, this topic will come back to the forefront.

### 4.4 REACH enquiries received by ECHA

In 2022, the ECHA Helpdesk received 2 772 enquiries related to the REACH regulation. As a result, it remains the regulation triggering the highest number of enquiries. The number of questions is in percentage terms overall comparable to 2021, but variation for the hot topics have been noticed and analysed below.

#### **REACH hot topics**

Registration was the area triggering the highest number of questions, representing 40% of the total number of REACH enquiries received by the ECHA helpdesk. First of all, companies continued to contact ECHA in relation to information requirements for new or updates of registration dossiers, and in relation to registration obligations, in particular related to data sharing and joint submission obligations. With the first registration deadline reaching twelve years old in 2022, an increase in requests related to access to twelve years old studies had also been noticed, when registrants did not manage to cooperate with their co-registrants, or when the registrants would like to access such data for read across purposes. This increasing number of questions on the topic is expected to persist in 2023. Many enquiries were also received in relation to substance identification, including requests related to on-going inquiry submissions. With the new requirement for only representatives (OR) to provide information

<sup>&</sup>lt;sup>15</sup> Guide on the classification and labelling of titanium dioxide: <u>d00695e4-e341-0a33-b0ac-bee35cb13867</u> (europa.eu)

on the non-EU manufacturer they represent that entered into force on 14 October 2022, ECHA also received many questions from ORs asking for clarification on their duties, or for more details on the type of information that they had to provide. Following some update campaign projects initiated by ECHA, the helpdesk also received enquiries from companies willing to update their NONS<sup>16</sup> registration dossiers. Overall, a slight increase in questions on registration was noticed compared to 2021.

Communication of risk management advice through the supply chain was the second area triggering a high number of questions, consisting of about 16% of REACH questions received in 2022. Amongst these questions, substances in articles was the main area, accounting for about 13% of the questions received on REACH. Most of these questions were about requirements for substances in articles and covered enquiries on SVHC content in articles, notifications under Article 7(2)) and obligations to communicate along the supply chain in accordance with Article 33. Questions on SCIP notification obligations under the Waste Framework Directive (WFD) continued to be received. However, an important drop by 37% of regulatory questions on Substances in Articles compared to 2021 was noticed, and it is probably caused by the fact that SCIP notification obligations for companies were better understood.

Authorisation came third in terms of the number of questions received, representing nearly 13% of the enquiries received on REACH. About two third of these questions touched upon specific issues related to applications for authorisation and the notification obligation for authorised uses under Article 66. The later included annual monitoring obligations, mostly for hexavalent chromium (chromium(VI)). Furthermore, a peak of questions was observed in relation to the recommendation for inclusion of lead in the Authorisation List during the public consultation, which was launched by ECHA in February 2022.

Evaluation was the fourth most popular area, representing around 10% of the questions on REACH. The questions were typically about requests for extension of deadlines for testing, consequences of dossier updates after receiving a draft or a final decision, consequences of cessation of manufacture or import after a draft or a final decision has been received, and data sharing issues during the evaluation process. In particular 2022 saw a change of practice following the BoA decision in joined cases A-006-2020 and A-007-2020. As a result, ECHA started to take into account, after July 2022 and under certain conditions, tonnage downgrade communicated with appropriate evidence submitted after the issuing of a draft decision and up to the adoption of the final dossier evaluation decision. This new practice triggered quite a number of evaluation questions.

Finally, Restriction made 8% of the total REACH questions received. Enquiries were mostly related to the following existing restrictions entries: entry 75 on tattoo inks; entry 74 on diisocyanates; entry 72 on CMR substances in clothing, textiles, and footwear; entry 68 on perfluorooctanoic acid (PFOA) and its salts in relation to the POPs Regulation; and entry 51 on phthalates in articles. Moreover, requests for clarification on the scope of upcoming restrictions such as PFAS, microplastics and formaldehyde restriction proposals were also received. An increase of this type of question is expected in 2023, with, for instance, the PFAS universal restriction proposal publication.

### 4.5 Technical enquiries received by ECHA

The IT external helpdesk provided support to industry, authorities, and other stakeholders on ECHA's IT tools (REACH-IT, R4BP, ECHA submission portal, IUCLID and Chesar) and

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<sup>&</sup>lt;sup>16</sup> Substances notified in accordance with Directive 67/548/EEC.

information disseminated on the ECHA website. National helpdesks have limited technical competence and most technical questions are channelled to ECHA.

In 2022 the ECHA IT external 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.

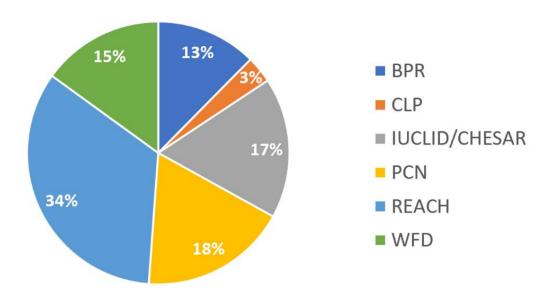


Figure 10: Technical enquiries received by ECHA in 2022

#### **Breakdown of questions**

Technical REACH questions ranged from dossier creation, dossier submission, legal entity changes, requesting submitted dossiers, only representative account management and inventory management.

In PCN, ECHA received questions on dossier creation, quality warnings, submission failures and account management. In IUCLID/CHESAR questions related to desktop and server installations, upgrade and migration, functionality issues, and import, export, and backup of dossiers.

In WFD the questions ranged from dossier creation, grouping, dossier submissions, business rule failures, TARIC code updates, SVHC lists, dissemination searching and delays. Finally, in BPR the questions were mostly related to R4BP 3 functionalities and the relationship between regulatory processes and their technical implementation.

#### **Dissemination**

ECHA dissemination pages have outgrown their initial design and are reaching the end-of-life stage. Some pages and functionalities (e.g., filtering and advanced search) have become less responsive and ECHA received many questions related to the dissemination platform on all legislations. These questions are likely to continue until 2025 when the new data availability system is planned to completely replace the current dissemination platform.

#### **Product support**

ECHA is responsible for the development and maintenance of several IT tools and applications and each of them follows a cycle of two major releases every year. In addition to these, there

are several intermediate bug fixes and patch releases. In 2022 ECHA had around 50 IT tool upgrades which occasionally triggered an increase in technical questions. The IT external helpdesk is the first point of contact for external users encountering issues with ECHA's IT tools. As a result, it contributes to their development via a continuous collaboration with the product and process managers, by assisting with the analysis of issues reported in the backlog and performing user acceptance testing before a product release.

#### Other enquiries received by ECHA

In addition to the enquiries replied to by the regulatory and IT external helpdesks and described above, ECHA receives additional questions from companies on specific areas or processes, e.g., regulatory and technical questions on the PIC regulation, questions related to on-going completeness checks, invoicing or SME verification. Those enquiries are addressed by the Units working directly on those processes and have not been counted in the figures presented above.

#### 4.6 Stakeholder and customer support

#### Communication channels and service response time

ECHA receives enquiries through its dedicated regulatory and technical contact forms<sup>17</sup>, as well as through other channels (e.g., ECHA Switchboard or functional mailboxes). The contact forms were revamped in 2022 to increase clarity and reflect the division of competences between ECHA and the national helpdesks.

The ECHA Helpdesk is committed to replying to regulatory enquiries within 15 working days. Depending on the workload and complexity of the question, this may take up to two months, as indicated in the ECHA Code of good administrative behaviour<sup>18</sup>. The questions are analysed as they arrive, and the easier or urgent questions are typically answered within a few days. While the overall median answering time is five working days, it varies per topic, reaching up to two months in the most complicated areas or when third party consultation (e.g., European Commission) is needed.

#### **Information resources and ways to support companies**

In 2022, ECHA worked on updating its available support material and developing new tools and guidelines to help companies to comply with their obligations in several areas.

- Guidance, manuals, practical guides and factsheets updates are available at <u>Guidance ECHA (europa.eu)</u>, <u>Manuals ECHA (europa.eu)</u> or <u>Home ECHA (europa.eu)</u>.
- Q&A (and FAQ) update and development: A new tool to publish ECHA Q&As was developed in 2022 to replace the previous section of the website. This new tool improves search functionality, adding multiple filtering options, and offers better navigation and user experience.

The Q&A database is available at <u>Questions and answers - ECHA (europa.eu)</u>. It includes more than 1 500 questions and answers about all processes and regulations under ECHA's remit, organised in topics, scopes and chapters to help companies easily find answers to their questions. Many of those questions have also been developed in cooperation with the national

<sup>&</sup>lt;sup>17</sup> Helpdesk support - ECHA (europa.eu)

<sup>&</sup>lt;sup>18</sup> Code of good administrative behaviour - ECHA (europa.eu)

helpdesks. They are marked as 'agreed with national helpdesks' and can be filtered in the NHD column in the tool.

This database is regularly updated and new Q&As are developed or other revised to reflect any change in the legal framework, new developments in relevant processes, or to address clarity issues identified from questions received by the helpdesks. In 2022, the following changes and main updates were made, among others:

- Restrictions: a new batch covering some general questions on restrictions, and the specific entries 27, 68, 73, 74 and 75 was published.
- o OR: revision and development of new Q&As related to the new requirement for only representatives to provide information on the non-EU manufacturer they represent.
- Sanctions: three Q&As were published on the impact of Sanction regulation on REACH (1925, 1926 and 1997).
- BPR and R4BP 3: bulk revision of all BPR regulatory Q&As, including the addition of new ones, removal of outdated ones, and the review and reorganisation of existing ones.
- SCIP: existing Q&As have been reviewed, and a few new Q&As developed to further support companies in using the SCIP database.

#### **ECHA** events

In 2022, after 2 years of remote working where virtual meetings became the norm, physical and hybrid meetings with externals started to be organised again at ECHA. The full list of ECHA events organised in 2022 and planned for 2023 is available at <u>All Events - ECHA (europa.eu)</u> and All Webinars - ECHA (europa.eu).

# 5. Cooperation between the National Helpdesks and ECHA

## **5.1 Queries redirected to the REACH and CLP national helpdesks**

To implement the new priority setting as outlined in the ECHA Programming Document for the years 2021-2024<sup>19</sup>, ECHA and the national helpdesks developed in 2021 a new way of working to transfer part of the regulatory REACH and CLP enquiries, both from EU and non-EU customers, at national level. This change did not affect the technical questions involving IT tools and applications that remained within ECHA's remit, nor the regulatory BPR questions, for which the existing division of competences between ECHA and NHDs remained the same.

This new division of work was implemented successfully along all 2022, during which 20% of REACH questions coming from EU customers and 18% from non-EU customers were redirected to the national helpdesks by ECHA. With reference to CLP, 28 % of the questions coming from EU customers and 25% from non-EU customers were redirected to the national helpdesks by ECHA.

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<sup>&</sup>lt;sup>19</sup> ECHA Programming Document 2021-2024

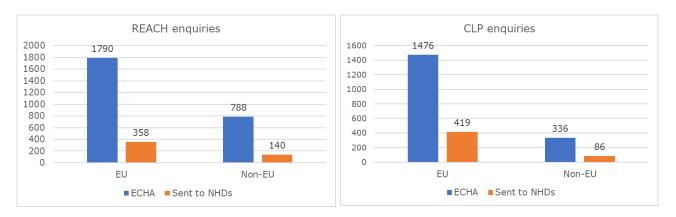


Figure 11: Total numbers of enquiries redirected to NHDs in 2022

Some NHDs noticed an increase in questions from non-EU companies. Others mentioned receiving queries from companies that were referred to them. However, overall, the NHDs did not notice a significant increase in the numbers of enquiries that could be linked to the redirection. NHDs also noticed that some of the companies redirected by ECHA have decided at the end not to contact them.

### 5.2 Steering Group meeting, workshops, and other activities

In 2022, ECHA and the national helpdesks continued to foster and further develop their cooperation through the HelpNet network. The 17<sup>th</sup> Steering Group meeting took place in Helsinki on 26 October 2022. The HelpNet Secretariat also organised two REACH workshops, two CLP workshops and two BPR workshops in May and October 2022. Those meetings included presentations from the European Commission, ECHA and the national helpdesks on different topics of interest, as well as break-out groups' discussion session and hands-on training. After two years of virtual meetings, the possibility to interact live at the October meetings was very much appreciated by the participants. The minutes of the meetings are available at HelpNet - ECHA (europa.eu).

In addition, HelpNet REACH members participated in two Forum training sessions on control of the Safety Data Sheets and its compliance with requirements of Annex II in November 2022. The BPR members participated to the training on CLP for biocides, in situ generating systems, and BPR borderline issues in December 2022. The NHDs provided good feedback on the possibility to take part in those training sessions.

HelpNet members and observers were informed on topics of their interest through the HelpNet updates issued in June and December 2022. To support the harmonisation of answers among all NHDs, ECHA also updated the HelpNet handbooks on authorisation, nanomaterials, CLP, PCN, dossier evaluation, restrictions and SCIP. Those handbooks are available at <a href="HelpNet-ECHA">HelpNet - ECHA</a> (europa.eu).

The majority of NHDs appreciated the new and updated support material available on the ECHA website. Some however suggested that support material and documents only available in English should be translated in other EU languages. NHDs welcomed the new Q&A web interface, providing some suggestions to further improve the tool. They also continued to use and refer to the HelpEx platform that they find very helpful and valuable to exchange views and interpretations with other members of the network. In addition, they very much appreciated the possibility to further discuss and exchange views at the new REACH and CLP videoconferences that are further described in the next section below.

#### **5.3 Videoconferences**

To support the increased work for the NHDs and enhance synergies and harmonisation with regard to difficult and hot topics, REACH and CLP monthly videoconferences were offered during 2022 to the NHDs. These regular exchanges complemented the existing cooperation tool (HelpEx) where questions could be posted, issues discussed, and interpretations shared between members of the network.

Five REACH videoconferences and four CLP videoconferences took place in 2022. Various questions were raised and analysed by the national helpdesks and ECHA during those events, with the objective of having a common understanding, agreeing on lines to take, and providing harmonised advice to stakeholders. Those videoconferences were also used to update members of the HelpNet on ongoing activities such as Q&A updates, FAQ proposals, or survey results. Following the success of REACH and CLP videoconferences, it was suggested to launch BPR videoconferences in 2023.

### 5.4 Borderline working group

The Borderline Working Group (BWG) was set up under the HelpNet in March 2021, to assess difficult cases of article versus substance/mixture definition based on difficult questions received by NHDs and ECHA.

The group consists in HelpNet members, Forum inspectors and ECHA experts as well as representatives of the HelpNet secretariat. The main output is the catalogue of borderline cases of substances in articles, a compilation of cases agreed by the members of the Working group and to be published on the ECHA website<sup>20</sup> in 2023.

In the 17<sup>th</sup> HelpNet Steering Group meeting of October 2022, the mandate for the BWG was extended until June 2024 to enable the group to discuss further cases and complement the catalogue when possible.

#### 6. Summary and conclusions

In 2022, the NHDs replied to almost 43 000 enquiries, and ECHA Helpdesk to almost 9 500 questions, counting both regulatory and IT tools related questions. The responses provided through the survey reflect the activities of the BPR, CLP and REACH helpdesks across 34 countries. Helpdesks of three candidate and one third country also reported on their 2022 activities, complementing the picture of the implementation of the chemicals' legislation in Europe.

The overall trend shows that the number of queries addressed to the NHDs and ECHA decreased after the peak in 2020, returning to pre-pandemic levels. BPR remains the regulation with the highest number of enquiries received by NHDs in the past eight years. The most popular topics were topics that fall within the remit of national authorities, i.e., 'National procedures and laws governing the transitional period', 'National fees and 'National authorisations of biocidal products or families'. For ECHA, REACH continues to be the regulation triggering the highest number of enquiries, in particular in the areas of 'Registration' and 'Communication along the supply chain'. For all helpdesks, the number of CLP enquiries decreased, although questions related to Annex VIII and PCN duties continued to require quite some support.

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<sup>&</sup>lt;sup>20</sup> Available at: 869ddf1b-288c-2265-88ee-b5dffdbdc684 (europa.eu)

HelpNet members and ECHA continued working together in 2022, increasing their cooperation with new ways of working. Videoconferences were organised to support the REACH and CLP NHDs, encouraging an increased exchange of information on topical issues between all national helpdesks. Similar events will be offered to BPR NHDs in 2023. After two years of virtual meetings, the network could attend the 17<sup>th</sup> Steering Group meeting, and the REACH, CLP and BPR workshops as live events in Helsinki in October 2022. The possibility to interact in person and take part in break-out group discussions was very much appreciated by the participants.

The ECHA HelpNet Secretariat will organise the 18<sup>th</sup> Steering Group meeting, and the regulatory workshops in Helsinki from 23 to 25 May 2023. In addition, meetings of the Working Group on 'Borderline cases on the article definition' will take place in February and April 2023, and monthly REACH, CLP and BPR videoconferences will continue to take place on a monthly basis throughout the year.

All in all, ECHA is committed to continue the enhanced cooperation and coordination with our national helpdesks, cooperation that will be of paramount importance with the upcoming CLP and REACH revisions, in order to maintain the high quality of our regulatory, scientific and technical advice to companies and stakeholders throughout the European Union.