



1 (15)

BPR Workshop

Opening by the Chair

The Chair (ECHA) opened the BPR Workshop by welcoming the representative of the European Commission (DG SANTE¹), National Helpdesks (NHDs) and observers. The Chair informed the participants about the change of the speaker under the item 3.2. (Vincent Dehon was replaced by Kristof Claes).

The draft agenda was approved as issued. No participant claimed a conflict of interest for any of the agenda items.

The Chair updated the participants on the Action point from the previous meeting. The <u>Coordination Group agreement on post-authorisation conditions related to shelf-life (CG-53)</u>² is now applicable to all national authorisation applications. The participants agreed with the Chair to close this Action Point. The Chair informed that the BPC-47 document '<u>Post-authorisation</u> <u>conditions for biocidal product authorisation: harmonising practices between national and Union authorisation</u>' was published on ECHA website, it was agreed with the Coordination Group (CG), that the CG-53 documents and the <u>CG-56 document Post-authorisation conditions</u> <u>for national and simplified product authorisation: harmonising practices</u>³ are applicable from 15 August 2023 (as of the date of publication of BPC-47) for all ongoing and new applications. This document summarises the topics discussed during the workshop (Annex I) and the follow-up action points (Annex II). The names of the participants attending the event are listed in Annex III to these minutes.

1. Updates from the European Commission and ECHA

1.1 Updates from the European Commission

Ligia NEGULICI (European Commission, DG SANTE) provided some highlights from the meetings with the BPR Competent Authorities (CAs). The presentation covered following topics: active substances (the extension of the Review Programme Regulation (RP), ethylene oxide/PT2), biocidal products (masterbatches), scope issue (monitoring products for rodents) and other updates (future evaluation (REFIT) of the Biocidal Product Regulation (BPR)).

Active substances:

As already announced at the HelpNet-18, since only 45% of the substances in the Review Programme have been evaluated, the legal deadline of 2024 will not be met. An extension of the Review Programme is needed.

The new deadline agreed with the CAs will be 31 December 2030. The Commission and ECHA initiated actions in 2017 to address the slow progress with the Review Programme, including discussions in the CA meetings, the survey of CAs conducted by ECHA in 2018 on the causes of delays, ECHA workshop on active substances in 2019 and ECHA's Active Substance Action Plan

¹ Directorate-General for Health and Food Safety

² CG-53-2022-07 AP 14.1 Shelf-life setting during PA_vf.docx

³ CG-56-2023-30 AP 14.1 Post-authorisation conditions for NA and SA_final

2020. Concerns about significant delays were expressed in Commission's Report in 2021 resulting in letters being sent to ministers responsible for biocides in the Member States. Discussions with MSs on the extension of the RP and other actions needed to accelerate the progress were initiated in 2023.

The Commission highlighted that this extension is not to be considered as a signal to decrease efforts in MSs nor as an opportunity for applicants to generate new data.

Other planned actions, to be agreed with MSs, are meant to improve the progress, like:

- removal of taking-over mechanism,
- prioritising backlog dossiers,
- respect of rules of procedure (e.g. application to be considered withdrawn when data requested is not submitted by set deadline),
- new guidance application: guidance agreed after 1 January 2024 will not be applied to evaluations of Review Programme substances,
- renewal of approvals: limited evaluation should be the target; prioritise Review Programme evaluations over renewals.

An action is foreseen from the COM regarding financial grants for CAs for 2023-2028, aimed at allowing CAs to hire additional staff.

Ethylene oxide/PT2:

After internal consultation with Commission services, it appears that the assessed use (industrial sterilisation of single use medical devices before these are made available on the market) and also other possible uses investigated by the Commission are considered out of the scope of the BPR but most likely falling within the Medical Devices Regulation. As a result, there is no use applied by the applicant for the substance within the scope of the BPR, which most likely will result in a non-approval decision. At the moment it is not possible to indicate the timelines when the procedure will be finalised.

Biocidal products:

Regarding the masterbatches, the Commission reminded that only masterbatches which confer biocidal properties are relevant for the BPR. In accordance with <u>CA-Sept15-Doc.6.2 – Final –</u> <u>Masterbatches</u> a masterbatch should be regarded as biocidal product if it has a biocidal function in the form in which it is supplied to the user. The same applies to masterbatches imported to the EU.

The Commission was informed about the companies making masterbatches available on the market without complying with the BPR requirements i.e. without being authorised. The discussions with the enforcement authorities are still ongoing.

Scope issue:

Monitoring products containing attractants to rodents have been under discussion at CA meetings in 2023. Such products (without a trap or with mechanical device to kill a rodent) do not contain biocidal active substance but only synthetic aroma without nutritional value, to attract the animals. Rodents leave the marks of their teeth and in this way the presence of the pest is shown. Such monitoring products are not in the scope of the BPR. Products need to be labelled to inform they are for monitoring purposes only. However, if associated with a lethal active substance, such products fall within the scope of the BPR.

REFIT of the BPR:

Finally, Ligia NEGULICI shared future plans as regards the upcoming evaluation of legislation in the context of Regulatory Fitness and Performance Programme (REFIT) for the revision of the BPR. The Commission has not decided yet on definite roadmap or timelines, but the first actions, like commissioning the study to the contractor will likely take place in end 2024. The Commission will also take into account the reports from Member States on the implementation of the BPR under Art 65(3), findings from the enforcement projects and the consultation with the stakeholders and citizens. The evaluation report by the Commission will most likely take be issued in 2026.

Discussion

ECHA asked if the feedback from ECHA will also be considered for the purpose of the BPR REFIT. The Commission confirmed that ECHA will be involved in this activity.

The Chair wanted to know if as new guidance agreed after 1 January 2024 will not be applied to evaluations of Review Programme substances, the same rule applies to the amendments of Guidance documents. The Commission tentatively agreed but the final confirmation from the Commissions services will follow (**Action Point**).

1.2 Enforcement activities of the Forum BPR Subgroup

Nicola TECCE (ECHA) shared the results of <u>Second harmonised enforcement project on</u> <u>biocidal products with approved/non-approved active substances - BEF-2.</u>

The inspections targeted biocidal products available on the market under the BPR and national transitional measures. The BEF-2 included horizontal obligations such as Article 95, advertisement, labelling and packaging of biocidal products. Sections on disinfectant products (product types 1, 2, and 4) and chemical analysis were also considered.

Overall, the objective of BEF-2 was to lead to a safer market of biocidal products and a level playing field among companies in the EU.

National enforcement authorities in **29 countries** (EU, EEA and Switzerland) selected autonomously companies, biocidal products (over 3 500), and active substances for enforcement, and carried out the inspections during 2022. Almost 80% of the inspected products were made available on the market under national transitional measures (Article 89 of the BPR).

The majority of product-types inspected were 2, 1, 18, 19. Many biocidal products inspected were disinfectants (due to COVID-19 pandemic).

63% of the inspected biocidal products in the BEF-2 were considered **fully compliant**.

About 60 of 220 different **active substances** were identified as non-allowed active substances (no longer supported in the review programme, used in the wrong PT, not an identified active substance or non-approval decision).

Overall, 37% of the checked **products** were **non-compliant** (either major 18% or minor 19% non-compliances) with at least one of the checked legal requirements.

Reasons for major non-compliances, which affected the **safe use** of biocidal products, were lack of product authorisation, presence of non-allowed active substances, severe non-compliances related to labelling and advertisement. Most biocides with such major non-compliance were disinfectants, insecticides, and repellents/attractants. All products that lacked authorisation or contained non-allowed active substances were withdrawn from the market. In

some cases, criminal complaints or fines were issued.

19% non-compliant products were found to have **minor** deficiencies where the national enforcement authorities gave advice or administrative orders.

Much non-compliance was found in **disinfectants** sold to consumers. 14% out of 1900 checked disinfectants were non-compliant. This included serious compliance deficiencies such as lacking authorisation or incorrect labelling that usually led to the withdrawal of the disinfectants from the market.

The compliance with **Art. 95 obligation** and the requirement of **labelling** in national languages were high. In 4% of 973 inspected products suppliers were not included in the Article 95 list. 8 % of 496 inspected labels were misleading.

As regards the **advertisement** (BPR Art. 72(1)), the obligatory phrase '*Use biocides safely*. *Always read the label and product information before use*' was missing in around 40% of 130 inspected products. 11% of advertisements were considered as misleading as per Art. 72(3) of the BPR.

The BEF-2 project provided the following recommendations:

- Member States should continue providing training and information campaigns to both national enforcement authorities and industry, aiming at improving knowledge on BPR requirements.
- Industry should increase their awareness about the legal responsibilities and ensure that the products contain only allowed active substances in correct concentrations.

In addition, Nicola TECCE informed about:

- the recent development of practical issues for enforcement and committed to share with the participants the most recent update of Manual of conclusions (**Action Point**).
- upcoming events to which HelpNet members will be invited (**Action Point**):
 - the BPRS Training for national inspectors on 1 December (on Summary of Product Characteristic (SPC) for biocides and related information on labels, biocides borderline issues, critical/forbidden claims),
 - BEF-2 Workshop with industry, planned on Q1 2024.

Discussion

ECHA asked if the speaker could share some examples of misleading advertisement or labelling found during the inspections. The speaker mentioned using cartoons to attract children. He highlighted also, that some of the companies were simply not aware of the legal requirements and restrictions.

1.3 Hot topics from ECHA Helpdesk

Malgorzata SZKLAREK (ECHA, REST) presented general statistics of BPR regulatory questions received by ECHA this year. The total amount of questions is returning to the levels observed in the pre-COVID years. She also shared examples of questions received by ECHA Helpdesk where internal consultation with operational units, Legal Affairs Unit or the Commission was triggered. Some of them were related to Art. 95 obligation e.g. inclusion of new suppliers on the list for the substance **Bardap 26** in the context of its **redefinition** to new substance identity (DMPAP) after the substance approval in PT8. She summarised the changes to Art. 95 list following the redefinition of Bardap 26 especially for PT8. Another example was related to the question send by a company who intended to submit Art. 95

applications based on **multiple letters of access** and wanted to benefit from the lowest possible fee for this type of submissions (2 000 EUR) as laid down in the <u>BPR Fee Regulation</u>. The speaker explained that the lowest fee can only be applicable for Art. 95 applications based on one letter of access to the complete substance dossier. For any Art. 95 applications where letter of access comes with any other complementary documents (in the form of the data or another letter of access) ECHA will charge higher fee.

Art. 95 (5) deadline is also still of interest, especially for in-situ generation systems covered by **Art. 93** of the BPR. In principle, for in situ generated systems covered by Art. 93 data protection periods are regulated by Art. 60 of the BPR. Active substances generated in situ that are being evaluated for possible approval in certain PTs under the RP for which the approval decision was not taken before 1 September 2013 fall under Art. 95 (5) and protection of the approval data will end on 31 December 2025. However, when a certain study has been submitted as part of the approval dossier for in situ generated system covered by Art. 93 and the same study has been used for the purpose of the evaluation of active substance/PT under the RP Regulation, such data will not benefit from the protection beyond 31 December 2025.

She also mentioned the fact that ECHA is being contacted by the customers whose national authorisations for AVK rodenticides has not been extended by CAs, the problems that the customers are facing with the **communication** with their respective CAs and lack of responsiveness from the eCAs.

Finally, the speaker summarised the **changes** to <u>ECHA subpage on the national transitional</u> <u>measures under Art. 89(2) of the BPR</u> and informed the members that ECHA is aiming to make the amendments every 3 months. She also reminded the participants about the **videoconferences** and invited the participants to submit their questions for videoconference scheduled for December 2023.

2. Updates from the Legal and Biocides units

2.1 Updates from the Legal Affairs unit

Tomas ZBIHLEJ (Legal Affairs Unit, ECHA) gave an overview of ongoing litigations: one appeal to the ECHA Board of Appeal on technical equivalence and three General Court cases (related to the renewal of creosote/PT8, the refusal of a union authorisation on permethrin and the non-approval of cyanamide/PT3, PT18). He presented the background information for each case and highlighted the noteworthy points of contention.

In brief, the assessment of **technical equivalence** performed by one of the CAs under the Biocidal Product Directive (BPD) has been brought to the Board of Appeal.

In the context of a biocidal product authorisation, the eCA had found the <u>alternative source</u> as equivalent to the reference source under the <u>BPD</u>. The <u>initial applicant</u> supporting the approval of the active substance challenged the assessment at national level and at the same time made an application of "non-equivalence" of its competitor's source to ECHA under the <u>BPR</u> Art. 54. ECHA rejected the application on procedural grounds connected to its admissibility.

The Board of Appeal has the on-going case where ECHA's decision under BPR Art. 54(4) has been appealed.

This generates the question who (e.g. only applicant) is allowed to apply for the assessment of technical equivalence and for what purpose.

Case T-9/23 on the **renewal of the approval of creosote/PT8** is linked to challenged

additional conditions on placing on the market articles treated with creosote (railway sleepers and electricity and telecommunication poles) imposed by <u>Commission Implementing Regulation</u> (EU) 2022/1950. As these conditions are not related to the placing on the market creosote itself or biocidal products, but that of placing on the market of treated articles, the question appeared if this measure is in line with Art. 4 (3) of the BPR and document agreed among CAs and the Commission (<u>CA-Nov14-Doc.6.2 - Final - Conditions on TA in approvals.doc</u>). Also, in line with the provisions of Implementing Regulation 2022/1950, treated articles in question may be placed on the market only in Member States that agreed on this and indicated on <u>Lists</u> of Member States where wood treated with creosote may be placed on the market for certain uses⁴. This generates questions related to the common market and the rule on not creating the barriers in the internal trade in the EU.

Case T-341/23 on a decision not granting the union authorisation for a permethrinbased product is based on the fact that the biodegradability study has not been considered by the eCA although, the study has been identified by ECHA as missing and draft Product Assessment Report (PAR) failed to pass the accordance check. Draft PAR was returned to the eCA. However, the eCA did not consider it necessary to consider the study as this assessment would not change eCA final conclusion and the recommendation to not to authorise the product. This case questions the role of draft PAR accordance check done by ECHA, the legal consequences of possible failure to pass this step and practical actions to be taken by the eCA.

Last case presented (T-536/23) concerns the non-approval of cyanamide/PT3, PT18 (Commission Implementing Decision (EU) 2023/1097) based on the fact that a safe use of biocidal product has not been demonstrated (recital 15). The approval application for cyanamide/PT3, PT18 has been submitted under the Biocidal Product Directive when the assessment of endocrine-disrupting properties was not a legal requirement. The substance belongs to backlog dossiers. After the publication of Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties, the Commission asked the Biocidal Product Committee (BPC) for the revision of its opinion. The applicant asked to submit new data, a request that the eCA did not consider necessary as it believed it had sufficient data available to determine the existence of the endocrine-disrupting properties of the substance. Despite the above, the eCA and subsequently the BPC concluded that while there was no question the substance had endocrine disrupting properties, it was not possible to conclude on the risks arising from the hazard. This lead to the adoption by the Commission of the contested non-approval decision. This case is linked to the questions on the assessment of endocrine-disrupting properties for **backlog dossiers** and how to address the issue of technical progress for such substances. It needs to be also clarified if the applicant has the right to submit additional information or its only at the eCA discretion. Also the legal value of the CA documents would need to be assessed.

2.2 Updates from the Biocides units

Claudio PUTZU's (ECHA) presentation covered information on SPC, guidance, recent publications and ECHA matters. The online training sessions for industry and on-site training for CAs in October had been much appreciated by the participants.

He started with an update on the state of play of the **SPC integration into IUCLID** and indicated SPC IUCLID project timelines. The go-live date has been postponed to Q1 2024. The

⁴ <u>https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles</u>

exact date will be communicated via ECHA website and newsletter. Since this date the SPCs will be prepared only in IUCLID.

Regarding guidance developments Claudio PUTZU summarised the publications that took place in 2023 i.e. update of the Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C) Version 6.0 where new sections for PT11 and PT12 were added and publications of two new documents: "Guidance on the analysis of alternatives" and (in cooperation with EFSA) "Impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water". The discussions on the implementation of the latter document are still ongoing with the CAs. He also gave an extensive update on the ongoing developments, especially the WG recommendations on technical equivalence for in-situ substances that is foreseen to be finalised in Q2 2024 and the Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides where the expected end date is Q1 2024 after consultations and discussions. Ongoing CHESAR platform project aims to harmonise the use of CHESAR for biocides and REACH. Discussions are ongoing at the working group level on resistance to antimicrobial active substances and products (France is the lead, supported by Germany). Guidance on Human Health, Part B+C will be updated due to new CLP hazard classes and revised information requirements (Regulation 2021/525). The priorities for the guidance update and development in the coming years has been presented to the CAs but the final agreement is still pending. In addition, the speaker also informed about planned guidance projects and update needs of ECHA Guidance for the coming years.

Regarding the **recent** publications the most important **BPC procedural documents** related to union authorisation (minor/major changes, post-authorisation) are available on ECHA website.

Finally he informed about the upcoming **satisfaction survey** that will we be launched in line with ECHA Programming Document 2023 – 2026 still in 2023 and also informed about the **staff changes** in biocidal units, welcoming Javier Sanchez Saez as new Head of Biocidal Products Unit and informing about the changes on the positions of team leaders.

Discussion

ECHA asked for the recommendations on the best ways of being kept informed about the publications of all the relevant BPR documents that are not only published on ECHA website but also come from CA and CG meetings and Official Journal. The speaker recommended subscribing to ECHA weekly, for OJ publication there is RSS feed and for CA and CG documents there is an option to activate the notification once the document is uploaded in specific folder.

2.3 Implementation of one substance – one assessment (1S1A) and potential impacts for biocides

Claudio CARLON (ECHA, Biocidal Substance Approval Unit) explained that one substance one assessment is an initiative, which is part of the Green Deal and is detailed in the Chemicals Strategy for Sustainability. It aims to **improve the efficiency**, effectiveness, coherence and transparency of the delivery of safety assessments of chemicals across legislation. The idea behind this approach is not to take over or replace the assessment performed under one regulatory framework by the evaluation made under another legal act but **to create synergies** and align opinions to be developed by various bodies, committees or institutions. In support to the implementation of 1S1A, an expert group composed of representatives of MSs, Commission and Agencies has been established. One of the main initiatives related to 1S1A is the horizontal legislative proposal on data that will create **one EU common data platform**, that will allow harmonised data dissemination, easier access and re-use of data and tracking of studies that has been commissioned by the companies. Biocidal active substances (AS) are frontrunners in this initiative as around 30% of them are also regulated under other EU food legislations e.g. <u>Regulation 1107/2009</u> (PPP Regulation). Hence, cooperation with EFSA and EMA e.g. in the guidance development is essential. Although the alignment is crucial, there are also some challenges e.g. the assessment is still performed under different regulatory frameworks, which is linked to different legislation processes, different scientific Committees and panels, different deadlines and variable Member States plans and legal barriers to re-use or share data e.g. due to different confidentiality provisions.

Further the speaker presented how the **enhanced collaboration** works in practice with EFSA for biocidal active substances being at the same time PPP active substances. It involves early identification of AS of common interest, connecting at the evaluation stage the biocidal eCA and PPP rapporteur Member State, involvement of EFSA and PPP rapporteur Member State in the BPC working groups and coordination of CLH proposals.

ECHA and EFSA have already been cooperating in the **guidance document preparations** e.g. ED guidance, Guidance on Impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water, the Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides. Claudio CARLON also provided practical examples on co-operation regarding etofenprox, deltamethrin, dinotefuran, sulfuryl fluoride, dinotefuran and tebuconazole. Finally, he highlighted that 1S1A is a **process requiring enhanced collaboration among actors** (Agencies, eCAs and companies). Time and support of new legislation (Data Regulation) are needed.

Discussion

One NHD asked if backlog dossiers will need to be re-submitted to align with the IUCLID format. Claudio CARLON replied that full AS dossier will need to be re-submitted in IUCLID format at the renewal stage, including the dossier submitted under BPD. This has been agreed with CAs and the Commission.

3. Topics presented by national helpdesks and observers

3.1 The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) experiences with harmonising mutual recognition procedures under the BPR

Cindy VAN DER MEER (Ctgb) gave an **overview** of the mutual recognition, explaining the roles of different actors and the phases of the processes in the Netherlands. She highlighted that the same procedure applies for renewal applications in parallel, and major and minor changes in parallel. However, union applications have a different process. Further she explained that all the information related to the specific referral are included in the outcome document that is publicly available on ECHA website and highlighted that the referrals are time and costs consuming tasks as reference Member State (refMS) must not only reply to all the comments made by the initiating concerned Member State (iCMS) but sometimes to also

perform once more some parts of the evaluation or the risk assessment.

Ctgb's **study on referrals** to investigate the effectiveness of the process indicated the peak in the number of referrals in EU in 2018 (almost 60). The highest share of referrals was initiated for PT18 and PT14 where more than 40% of peer-reviews per each product type led to disagreements. In general, most topics of referrals were related to human health and efficacy (almost 120 referrals per each topic). For PT14 products during first renewal of rodenticides the reasons of disagreements were dermal absorption values, shelf-life, packaging, efficacy. For PT18 products divergent views between refMS and iCMS were linked to the practicability and feasibility of risk mitigation measures proposed by refMS for consumers. Currently, on average more than half of referral cases lead to amendment of the SPC like amendment of use instructions, additional risk mitigation measures, non-authorisation (of uses), postauthorisation requirement.

Cindy van der MEER explained the **role of Netherlands** as iCMS and the **rules** followed by Ctgb when starting a referral. In general, Ctgb decides to initiate the procedure only where there is sound justification that there is a risk, that has not been identified by the refMS. If the final conclusion of the refMS remains the same when applying different approach preferred by Ctgb, the referral will not be initiated. 71% of referrals initiated by Netherlands has led to the amendment of SPC. However, when Netherland was acting as refMS, cMSs did not agree in 50% of the applications. This percentage could be the result of different level of pragmatism among MSs.

As an example of how the referrals could be avoided, Cindy van der MEER referred to **CG Working Party** that was created at the first renewal of rodenticides and was able to systematically harmonise the approaches among MSs. The results of Ctgb study were also presented to CG. The overview table is available in Interact Portal as a repository of the referrals that were already agreed on.

Finally, she shared **lessons learned** highlighting that it is crucial to identify the issues as early as possible in the process (especially at the pre-application consultation). The work done by different CG Working groups (e.g. on PT14 or WG on biocidal product family) is also highly appreciated. However, the improvement could be to agree the referrals not per specific product but rather to harmonise general approach that would be applicable to AS or product type.

Discussion

The Commission acknowledged the work done by Ctgb and expressed its gratitude for the study and especially the overview table with past referrals.

ECHA asked if further guidance on the SPC preparation is needed to enable harmonisation among MS and reduce the number of referrals. The speaker explained that although more guidance on the SPC preparation would be appreciated, it is more important to make more effort for the harmonisation of the scientific assessment among the experts.

3.2 Belgian survey on the use of biocidal disinfectant products and resulting action plan

Kristof CLAES on behalf of Vincent DEHON (Belgium Federal Public Service Health, Food Chain Safety and Environment) gave a presentation on the <u>study that aimed to assess the use</u> <u>of disinfectants in the Belgium population</u>. He explained the origins of the initiative, the

methodology and results and next steps taken by Belgium.

The reason for the study was the **large number of accidents** with disinfectants during the Covid-19 pandemic, as reported by the Poison Centre. The increased use of disinfectants was expected, but the increase in the number of accidents with these products was very striking – only for PT1 products 1600 incidents reported in 2020 and 1455 in 2021. For PT2 products the peak of the incidents was reached in 2020 with 915 cases. It was also noted that in 2020 the amount of PT01 biocidal products placed on the Belgian market was about 5 times higher than in 2019.

Specifically, the **objectives** of the study were to highlight, among other things, the following elements: the habits of use of these types of products, the product use presenting higher risks, the handling of the instructions of use, the purchasing processes, the influence of the Covid-19 pandemic.

To gain insight into the possible explanations for the accidents in Belgium, a **survey** was conducted where 2025 Belgians were contacted online or by phone in March and April 2022 about their use of disinfectants and the reading of the label. Three types of disinfectants were included in the survey: disinfection of the skin and scalp (PT01), disinfection of surfaces not in contact with food or feed (PT02) and disinfection of surfaces in contact with food or feed (PT04). The sample was adjusted to ensure that it was representative of the national population in terms of age, gender, province, level of education and degree of urbanisation.

The **outcome** of the survey indicated that biocidal products were **widely used** by the Belgian population: in the last 12 months, 66% of the respondents used PT01, 67% used PT02 and 44% used PT04 (by their own initiative, a habit or choice). The Covid-19 pandemic had a clear impact on the use of disinfectants: the frequency of use has been significantly higher since the crisis.

With regard to **PT01** products, the majority of the respondents indicated the use of such products as preventive measure against Covid-19. A little more than a third of the Belgians wrongly believe that PT01 disinfectants have cleaning properties (56% users), 54% of respondents are not aware of the contact time required for effective disinfection or the expiry date of the product, 4% have already mixed the disinfectant with another product. With regard to **PT02 and PT04** lack of knowledge regarding expiry date, required contact time, and dilution or rinsing of surfaces after use (PT04).

The study showed that one of the main **reasons for non-compliance** with instructions for use and safety is that the information on the packaging is not read. Around 30% of respondents do not read the label at all. 14 – 18% of the users find the information on the labels mainly unclear (not clear at all or not very clear) mostly because of 2 reasons: poor readability (too small fonts, too much information, bad contrast between text and background) and the terminology (difficult to understand, language that is 'too scientific'). 16% of respondents have encountered health issues after using PT01, PT02 or PT04 products: in the vast majority of cases they experienced skin irritation (75%), burning sensations or allergies but the problems in most cases had not required medical consultation. What emerges from this study is that the current risk assessment can underestimate the exposure of the population and the release in the environment.

Belgian authorities launched a **communication campaign** for the general public including cooperation with schools. The cooperation with industry associations aims to improve the packaging or labelling: the development of pictograms to inform about contact time or the need to rinse the surface after use could be developed. The surveys on the use of other PTs

may also be considered for the future.

Due to the unexpected change of the speaker, the Chair asked the participants to post their questions in the chat or send them to the HelpNet functional mailbox. The questions will be collected by the HelpNet Secretariat and forwarded to the Belgium Federal Public Service Health (**Action Points**).

Closing of the BPR Workshop

The Chair listed the action points and thanked participants for the interesting discussions. The Chair invited the participants to reply to the satisfaction survey which will be sent after the meeting and closed the BPR Workshop, until the next one foreseen for spring 2024.

Annex I – Agenda of the BPR Workshop

BPR Workshop

Chair: Erwin ANNYS

BPR Workshop (11:00-16:45, Helsinki time)

Opening by the Chair

1. Updates from the Commission and ECHA's Support and Enforcement unit

- 1.1 Updates from the European Commission (DG SANTE, Ligia NEGULICI)
- 1.2 Enforcement activities of the Forum BPR Subgroup (ECHA, Nicola TECCE)
- 1.3 Hot topics from ECHA Helpdesk (ECHA, Malgorzata SZKLAREK)

Lunch break

2. Updates from the Legal and Biocides units

- 2.1 Updates from the Legal Affairs unit (ECHA, Tomas ZBIHLEJ)
- 2.2 Updates from the Biocides units (ECHA, Claudio PUTZU)
- 2.3 Implementation of one substance one assessment (1S1A) and potential impacts for biocides (ECHA, Claudio CARLON)

Coffee break

3. Topics presented by national helpdesks and observers

3.1 The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) experiences with harmonising mutual recognition procedures under the BPR (Ctgb, Cindy VAN DER MEER)

3.2 Study on the use of biocidal disinfectants among the Belgian population

(Federal Public Service Health, Food Chain Safety and Environment, Kristof CLAES)

A.O.B.

Conclusions of the day

Closing the BPR Workshop at 16:45

Annex II - Action points

No	Action	Agenda item	Responsible	Status
1.	Inform weather the guidance updates will be applicable to the Review Programme substances.	1.1	Commission	Open
2	Share the manual of conclusions with BPR members.	1.2	HelpNet Secretariat	Closed
3.	Invite NHDs to the BPRS training for national inspectors on 1 December 2023 and share the link to the Workshop with Industry ⁵ in Q1 2024.	1.2	Forum Secretariat	Closed
4.	Forward to the presenter the questions ⁶ received by e- mail (<u>help-net@echa.europa.eu</u>).	3.2	ECHA	Closed
5.	Reply on questions received on the presentation.	3.2	BE HD	Closed

 $^{^5}$ The workshop will be attended only by BPRS members and a limited number of accredited stakeholders. 6 No questions were received after the meeting on the topic.

Annex III - List of participants

Country	Name, surname
Austria	Natalie HOFMANN, Peter SCHINDLER
Belgium	Kristof CLAES
Bulgaria	Viktoriya HRISTOVA
Croatia	Ivana VRHOVAC FILIPOVIC
Denmark	Clara FORRAI OERSKOV, Lone KÆRGAARD
Estonia	Riina LAHNE
Finland	Hannu MATTILA
Germany	Juliana REY, Jessica JORDAN, Oliver BRYLSKI
Hungary	Henrietta HAGYACKIJ-SZABÓ
Ireland	Louise PIERCE
Latvia	Evija PORIKE
Lithuania	Evelina BARONIENE, Palmira HAKAITE
Luxembourg	Jeff ZIGRAND
Netherlands	Cindy VAN DER MEER, Evan BEIJ
Norway	Karina PETERSEN
Poland	Agnieszka BARANOWSKA-MOREK, Aleksandra WILCZYNSKA, Joanna WÓJCIK, Marek JUSZCZUK, Marta OSÓWNIAK
Romania	Mihaela-Simona DRĂGOIU
Slovak Republic	Jadža PORUBIAKOVÁ, Maria SKULTETYOVA
Slovenia	Marta PAVLIČ ČUK
Spain	David CANO GOMEZ
Sweden	Leif BENGTSSON, Theresa HOL

European Commission

DG	Name, surname
DG SANTE	Ligia NEGULICI

Third Country observers

Country	Name, surname
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Country	Name, surname
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Switzerland	Olivier BLASER, Silvia NANNI

Industry observers

Organisation	Name, surname
A.I.S.E.	Elodie CAZELLE
Cefic	Boris VAN BERLO

ECHA staff

Unit ⁷	Name, surname
A2	Anisa KASARUHO
A2	Anna-Liisa PIKKARAINEN
A2	Elena BIGI
A2	Erwin ANNYS
D1	Inka ORA
D2	Irina POPESCU
D2	Janez BRAJER
D2	Javier SANCHEZ SAEZ
D4	Katja ORISPÄÄ
R3	Konstantinos ANAGNOSTAKIS
A2	Laura CHAMAK
A2	Laure PAIN
D2	Lucie BIELSKA
A2	Malgorzata SZKLAREK
D1	Micaela DAMSTEN
ED0	Minna STROMBERG
D2	Roberto GILIOLI
D2	Rodrigo TAVARES RIBEIRO
A2	Roxana BROASCA
A2	Ruben GONZALEZ
A2	Sofiya KOVALYSHYN
D1	Timo ROCKE
A2	Viorica NAGHY

⁷ ECHA – organisation: <u>https://echa.europa.eu/about-us/who-we-are/organisation</u>