BPR Workshop – 23 May 2024

1. Opening the HelpNet CLP Workshop

1.1 Opening by the Chair

The Chair **Elena BIGI** (ECHA) opened the BPR Workshop by welcoming the representative of the European Commission (DG SANTE[1]), national helpdesks (NHDs) and observers.

This document summarises the topics discussed during the workshop (Annex I). The names of the participants attending the event are listed in Annex II to these minutes.

1.2 Follow-up of action points and approval of the agenda

The Chair reported on the list of action points from the BPR Workshop held in November 2023. Regarding AP1 the COM informed that neither new guidance nor updated versions of existing guidance agreed after 1 January 2024 are applicable to active substances being still evaluated under the Review Programme Regulation (RP). Hence, the Chair closed all actions points.

1.3 Approval of the draft agenda

The Chair presented the draft agenda of the day, which was approved without comments.

Then, the Chair requested the participants to declare any conflicts of interest that they may have on any particular agenda points. No conflict of interest was raised.

In addition, HelpNet members were asked to verbally express their concerns[2] (if any) on the attendance of observers on any agenda points. No objections were raised.

2. Updates from the European Commission and ECHA

2.1 Updates from the European Commission

Ligia NEGULICI (European Commission, DG SANTE) began her presentation by giving an update on the discussions taking place at the CA meetings related to **the extension of the RP (Review Programme)**. She communicated that the delegated regulation which amends Article 89 (1) of the BPR to extend the deadline of the RP to the end of December 2030 was just published in the Official Journal. In addition, she informed about possible changes in the Review Regulation (Regulation (EU) No 1062/2014) such as: removal of the taking over mechanism, changes in the provisions related to joining or replacing participants by mutual agreement, possible new provisions related to the submission of the data especially in relation to the ED properties where the deadline of the submission (31 December 2026) has been already agreed with Member State Competent Authorities (MSCAs).. She also reminded of other actions aimed at speeding up the progress of the RP agreed with MSCAs such as: prioritizing backlog reports, respect of the rules of procedures, not applying new guidance and updates of existing guidance adopted after 1 January 2024 in the ongoing evaluation of RP active substances (AS), limited evaluation for the renewals as target, prioritization of MSs Review Programme evaluations over renewals and financial grants awarded by the COM, allowing MS to allocate sufficient resources to fulfil their regulatory tasks.

The speaker continued with the topic of **restriction proposal** under REACH for **skin sensitisers**

[1] Directorate-General for Health and Food Safety
[2] According to the Handbook, section 1.2 Chair of the HelpNet Steering Group, the 'Chair considers and takes decisions on any objections from members to the participation of observers or additional experts.

in certain articles available for general public. The proposal covers in total 94 substances listed in Annex VI to the CLP Regulation with harmonised classification as skin sensitisers cat 1, 1A and 1B and additional substances with skin allergenic properties (~24 disperse dyes) for which no harmonised classification under the CLP Regulation has been established. RAC-SEAC opinion recommended the exclusion from the scope of restriction proposal skin sensitizers regulated under the BPR to avoid double regulation. The consultation organised by the COM indicated though that the majority of MSCAs considered that BPR does not guarantee adequate protection, in particular as it only regulates the placing on the market of treated articles (and not their entire supply chain) and supported a non-derogation. The COM is now reflecting on the results and developing a common line to be transmitted to DG GROW..

Furthermore, Ligia NEGULICI updated the participants on ongoing revision of Working Group recommendations on the evaluation of in-situ active substances and biocidal products. The conclusions of the working group are now being consulted with the MSCAs. The final approval and publication of revised recommendations is expected for December 2024. Two main assumptions for the working group were:

- for active substance approval (and subsequent product authorisation) the whole in-situ generation system needs to be assessed – especially the parameters of the device used for in-situ generation of representative product, that the prospective applicants for product authorisation would need to know;
- at product authorisation stage the differences in the device or conditions of use may result in variation of the composition of the active substance. Such variations should be acceptable, provided that the prospective authorisation holder provides additional data on AS that will be handled in accordance with already agreed procedures.

The working group provided also conclusions related to the assessment of technical equivalence (TE) for in-situ AS. In particular, it concluded that, while for in-situ AS technical equivalence appears not feasible, reference specifications should be defined at the approval stage only for precursors marketed for biocidal purposes; whereas for precursors made available on the market without biocidal claim (commodity chemicals) the approval should include the reference to agreed standards.

Further, the COM informed about **derogations** granted in 2023, covering around 180 derogations under Art. 55 (1) mainly for disinfectants and under Art. 55 (3) for in-situ generated nitrogen, that has been recently included in Annex I to the BPR. Hence, for in-situ nitrogen-based products simplified authorisations are expected to be granted. COM also asked NHDs if they are getting questions related to derogations.

Ligia NEGULICI concluded her presentation with the upcoming **amendments of "Same BP Regulation**" (414/2013) and '**Renewal Regulation'** (492/2014). The changes to the SBP Regulation to be presented as draft regulation at the Standing Committee in June, would focus on keeping SBP identical with related reference product, clarification of the alignment of the expiry date of same BP with that of the reference product and introduction of the procedures for the renewal of same BP authorisations. The changes to the Renewal Regulation, to be presented as draft Regulation in Autumn 2024, would focus on the introduction of the procedures for the renewal of same BP authorisations, changes during renewal and referrals to the Coordination Group.

Discussion

One NHD wanted to know what will happen to the already authorised same biocidal products (SBP) if they differ from the reference product. Ligia answered that the COM is still reflecting about this issue. Itis likely that some transitional provisions will be proposed in the draft regulation.

On questions related to derogations, Malgorzata Szklarek (ECHA) commented that ECHA was receiving such enquiries during the pandemic but not any longer.

2.2 Updates from the biocidal units

The chair introduced the next speaker **Javier SANCHEZ SAEZ** - Head of Biocidal Products Unit (D2).

Javier SANCHEZ SAEZ started his presentation with **an update on active substance approval** highlighting the fact that after a reduction at the beginning of the year, the number of BPC opinions projected for 2024 is around 20, reaching the same level as in 2020. Of those, 60% are related to the RP, 20% to renewals and 20% to new AS. Further, he gave the reasons for the merge of the two consultation procedures for AS being candidates for substitution under Article 10 (3) of the BPR (during BPC opinion forming) and for approval of AS subject to exclusion criteria under Article 5 (2) of the BPR (after BPC opinion is delivered to COM). The merge of the two in one single consultation aims at obtaining purposeful information earlier in the process, to provide guidance and instructions about which data is needed and how information from the third parties is addressed.

Javier informed about the obligation to provide **active substances renewal data into the IUCLID format** instead of Word and PDF formats. He affirmed that the only way to be able to provide information in one common data platform with data from different regulations is to have the information in a structured format such as IUCLID, and this would also facilitate reuse of the information and disseminating it to the public. The objective would be to have the system in place by spring of 2025. He highlighted that from July 2026, companies should submit application for renewal with full data package in IUCLID.

He continued with the update on **Union authorisations** (UA). The forecast for the BPC opinions in 2024 is 18. He also reported on the countries acting as evaluating Competent Authorities (eCAs) with Netherlands (54 applications) and Germany (30 applications) in the lead. Also, he mentioned the new webpage with information useful when preparing a UA, such as when to approach the eCA, applicable national fees, procedures and the contacts of the eCAs.

The last part of the presentation was dedicated to the **ongoing guidance projects** (CHESAR platform, Guidance on Human Health, Part B+C, Resistance to antimicrobial active substances and products and Guidance Vol V on disinfection byproducts). Javier mentioned also the guidance documents planned for the revision in the coming years i.e. Volume IV, Environnement, Part A, Guidance on active substances and suppliers (Article 95 list), Guidance on applications for technical equivalence.

Discussion

Malgorzata SZKLAREK (ECHA) wanted to know which dossiers (at the evaluation stage) would be affected by the new procedure. The speaker replied that the aim was to include all the ongoing evaluations except the ones which are already very close to the end of the evaluation (or applications already in the peer review) which will follow the old procedure.

One NHD asked what data (only renewal data or also the initial approval data) should be submitted in IUCLID format from July 2026. Javier replied that the aim was to include the whole package (old and new data).

2.3 Updates from the Legal Affairs unit

Camilla BUCHANAN (ECHA, LAU) started her update with the judgement in case T-297/21 Troy v Commission related to the approval of **carbendazim**. The approval was granted only for three years as carbendazim is classified as mutagen 1B and reprotox 1B, whereas the BPR gives the possibility of 10 years approval. The Commission decided also to impose a ban on the use of carbendazim on treated articles, which was actually a more restrictive approach than the BPC opinion. The applicant challenged the Commission's decision but the application was dismissed.

The Court confirmed that the Commission is not obliged to follow the BPC opinion and has a margin of discretion at the stage of adopting its decision Hence, the Commission is entitled to impose specific conditions on treated articles on the basis of Article 58 of the BPR.

Then the speaker proceeded to announce the proposal of the **Common Data Platform Regulation** and its key provisions. At the moment the proposal is awaiting the first reading at the European Parliament (expected after summer) under the ordinary legislative procedure. The main idea would be to bring together data on chemicals and information generated under the EU chemicals regulations and held by EU agencies to enable better comprehensive, consistent, and scientific robust assessments of chemicals and ensure the best use of existing information. ECHA was given a task to manage the whole database. The EU agencies will be required to submit data to this platform and national authorities will have the right to reuse that data. She highlighted that the platform is **not** to be used to fill data gaps by the authorities on behalf of the applicants. The burden of proof stays with the applicants who still have the legal obligation to submit required data. In other words, the applicants cannot rely on the data from the database and they cannot e.g. refer the authorities to the common data platform for the purpose of their application. This database will be publicly available respecting confidentiality claims as per the relevant regulations under which the data would be submitted.

Finally, Camilla mentioned the ongoing update of *Special Series Practical Guide on Letters of Access* and The *Guidelines for assessing the confidentiality of the information in assessment reports* - both to be presented to the CA meeting in September 2024.

Discussion

The Chair asked if it the obligation to notify all the commissioned tests under the Common Data Platform Regulation will also apply to biocides. The speaker confirmed and explained that it was inspired by an EFSA rule that states that companies need to notify EFSA when making a study. The reason for this is to avoid "cherry picking". The notification obligation will cover the BPR and all other regulations across Europe that are affected by the Common Data Platform Regulation.

3. Topics proposed by HelpNet members and observers

3.1 Updates on Summary of the Product Characteristics (SPC) integration into IUCLID

Roberto GILIOLI (ECHA, team leader of Horizontal support team in Biocidal Product Unit (D2)) gave an update on the SPC-IUCLID integration. He highlighted that it is important to have all the information on chemicals to be extracted jointly from one place.

IUCLID is at the cornerstone of ECHA's data strategy, in the long term it is supposed to be the repository of all scientific information received by ECHA. Therefore, it was a strategic decision to transition the SPC editor to IUCLID. ECHA tried to preserve the same content as in the SPC editor with a different format. The SPC in IUCLID went live on February 12th, 2024, with all SPCs in R4BP3 cases and assets migrating automatically, except for SPCs attached to ad hoc communications and messages. The speaker reminded that as of this date, SPCs are to be prepared only in IUCLID format (.i6z) and that as of this date there is no more access to the SPC editor. Roberto GILIOLI explained that IUCLID can be accessed through ECHA's cloud services (which is constantly updated) and by downloading a standalone version. Roberto then described and illustrated with screenshots how to download migrated SPCs in R4BP3 and how to import and open SPCs in IUCLID.

Roberto mentioned that one issue identified after going live was related to the document names for example product family IUCLID document names are not transferred to R4BP3. Roberto concluded the presentation by showing the information resources that can be found in different sub-page of the SPC ECHA website.

Discussion

One NHD asked if it is possible to manually change translated text e.g. if precautionary phrases are not aligned with the translations as in the CLP Regulation. The speaker explained that precautionary phrases are hard coded information and are not editable. He advised to contact the ECHA Helpdesk, should any deviation bespotted. ECHA will include such requests in a following release of IUCLID.

Another NHD questioned about the disadvantages of stand-alone version of IUCLID and also mentioned that in IUCLID it is difficult to find in the SPC the manufacturer of the active substance.

Roberto answered that the biggest disadvantage is the management of the data. After each IUCLID release the stand-alone version needs to be uninstalled and new version re-installed on the user`s computer. It requires prior data extraction (SPCs and dossiers), storing them locally and uploading back to the system after installation of new IUCLID version. The advantage of the cloud version is that the updates take place automatically. For the AS manufacturer, this will be cover in the next presentation.

Another NHD wanted to know if using cloud version the user has access to other users` SPCs within the same Legal Entity (and possibly can modify or delete them) or only to the ones that the specific user is working on. Second question was related to the linguistic review of the SPC. NHD wanted to know which master SPC should be used when the English version and the word version with track changes generated during the evaluation process are not the same. Third question was related to mistakes in the previous SPC editor such as commas and square meters. The enquirer wanted to know if those issues were fixed in this new version and if not when they will be fixed.

Roberto explained that the cloud visibility is organized by the legal entity. Whoever in the eCA has access to the cloud account can see the work of other users. He mentioned a feature in IUCLID which notifies the user that they are trying to upload a document that has been already uploaded by someone else. He advised also for those who want to work on their own to download the standalone version of IUCLID. Although the cloud version and desktop versions don't communicate with each other, after finishing the work, the user can export the data from stand-alone version and upload it to the cloud.

On the linguistic review of the SPC, as this is more regulatory aspect the speaker advised to liaise with the applicant who is preparing the translations and the eCA to focus on the content. He also reminded that for UAs the last actor is the COM.

On the issues related to points, commas, square meters (or other not typical units of measure) he suggested requesting such changes via ECHA helpdesk.

The COM commented on the linguistic review and highlighted that the applicant should provide an updated English master SPC version. In principle, there should be no non-alignment with the word version and that the COM will look into this when they start new linguistic reviews.

3.2 SPC for Biocidal Product Family

Ruben GONZALEZ VIDA from A2, IT external support Helpdesk team introduced the concept of "sameness" using the SPC of biocidal product family (BPF) to illustrate its meaning. He also presented the business analyst perspective.

He highlighted that from the business analyst point of view "sameness" is defined by the

differences. To identify those differences the data needs to be structured and chronological as the difference may appear over time. The data need also to be comparable, integrated and reusable. He emphasised that the sameness in case of BPF may have different meaning as a legal term (grouping of *products* based on the sameness criteria) and as a business term (grouping of IUCLID *data* based on the sameness criteria.

He explained that there are three levels of the SPC for BPF: Level 1 is common to all products and metas within a family, level 2 Meta SPCs: are biocidal products grouped based on the sameness criteria and level 3 - concerns the product information. From the IT perspective there is also an additional level 0 that corresponds to reusable dataset within the SPCs used by the applicants. When it comes to the definition of meta SPC, the speaker reminded of four criteria for grouping products (similar composition, similar uses, the same H and P phrases, a common set of first aid instructions, disposal, storage and shelf-life).

He followed with a demo showing all the information levels, highlighting different perspectives for eCAs/NHDs and the applicants when dealing with a SPC. He demonstrated how to navigate and how to find the relevant information, e.g., with an example of AS manufacturer. He demonstrated how an applicant can follow a bottom-up approach whereby repeatable elements from level 0, 1 and 2 can be created firstly and reused later in the different sections of a family SPC. He showed also the function "compare" that allow to immediately spot the changes e.g. between the authorised SPC as and draft SPC submitted with the change application.

He concluded the presentation stating that identifying the sameness is essential to initiate an analysis and that the IT tools help users to use the reusable elements and to determine the sameness of the data.

Discussion

There were no questions but in the presentation the speaker addressed the question related to AS manufacturer asked for the agenda item 3.1.

3.3 Challenges with mutual recognition and same biocidal products application

Karolina PASTUSZKO (Poland, The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) started her presentation with the statement that in theory mutual recognition (MR) should not create major problems as the procedure as set out in the BPR is relatively simple. However, the challenges arise when implementing those provisions in practise. Karolina highlighted the role of NHD as the first contact point for prospective applicants in raising the awareness of the companies intended to apply for MR and/or same biocidal product (SBP) about possible issues they may be faced with. The speaker emphasised also the experience of Polish eCA, that granted around 600 authorizations under the BPR so far, of which 90% via the MR or SBP.

Then the speaker explained the procedures, similarities and differences between MR and SBP. Karolina also highlighted that MR procedures (especially mutual recognition in sequence - MRS) should be used in the first instance to open additional markets in another MS, whereas SBP authorisation should be considered as a "copy" of already granted or about to be granted authorisation in the same MS. Karolina also explained from the perspective of future applicant and the perspective of the reference Member State (refMS), the advantages and disadvantages of mutual recognition in parallel (MRP) and MRS.

The main strategy for MRS should be to open additional markets whereas for mutual recognition in parallel (MRP) the key market MS should be involved from the very beginning of the process. For the refMS, MRS is less favourable as it consumes more time and resources, without financial

compensation (e.g. in Poland) for the additional work done by the refMS when replying to comments submitted by cMSs after the authorisation is granted and in different timelines e.g. in Poland. The other disadvantage of MRS is the fact that in cases of inconsistencies spotted by a cMS the amendments of the SPC requires also the changes application, followed by administrative decision.

Furthermore, the speaker explained the difference in the length and the timelines of commenting periods for MRP and MRS, MRS and the ongoing changes and the overlap with the ongoing renewal of authorisation in the refMS.

She continued explaining the links between MRP and the authorisations granted under the transitional measures. The issue for submission of MRP before the AS approval date could be e.g. not paying ECHA fee that results in the termination of the R4BP 3 case and withdrawal of the transitional authorisation. It also means that the products cannot be made available on the market and benefit from Art. 89 (2) of the BPR. She also explained the close relationship between MRP linked to SBP and the transitional authorisation, highlighting that the issues with MRP application will also affect the SBP application.

She continued with the SBP applications and possible scenarios: SBP where related reference product is single product, whole BPF, one member of the family and reduced BPF (i.e. reduced number of meta SPCs). The last option, although included in ECHA`s practical guide on SBP authorisation, in the speaker`s view it may create issues as it is questionable from the legal point of view. Hence, the work-around implemented by Polish eCA is to authorize the reduced family only in cases where the differences between authorization of the reference related biocidal product family and the same biocidal product family can be covered by administrative changes listed under title 1 section 2 point 8 or/and 9 of the annex of regulation 354/2013. This solution allows to remove certain META SPCs and create reduced family if removal of those META SPCs is an outcome of a removal of certain uses, claims, target organisms or category of users.

She wrapped up the presentation with recommendations for NHDs when providing advice to the prospective applicants:

- to promote MRP as main strategy for MR (as preferable option by the refMS), and use MRS only when there is a need to open additional markets in the EU;
- to raise awareness among the prospective applicants of the dossier submission step (compliance check by ECHA) and payment of ECHA submission fee for MR as those may be crucial to keep on the market products made available on the market under the transitional measures (transitional authorisations)
- to highlight to the prospective applicants that the timing of the submissions of renewal and changes applications should be carefully considered bearing in mind the expiry date of the reference product;
- to emphasise to the prospective applicants that any differences between the SBP and related reference products, should be investigated in detail, especially in case of BPFs.

Discussion

Ruben GONZALEZ VIDA (ECHA) commented that the submission of MRS application is part of the company business strategy, and it may not be always possible to direct the customers to the MRP or recommend it as the main strategy, as such submissions may not always be possible.

The speaker agreed but also emphasised that according to her experience as The Chair of the Coordination Group the most difficult referrals were related to MRS. In her view, it might be beneficial for the prospective MRS applicants to be aware of this.

One NHD asked if when SBP and related reference product are manufactured by different companies, Polish eCA requires from the SBP applicant some kind of evidence proving that SBP

and the related reference product are identical or if the written of SBP applicant on the sameness of both products is acceptable by the eCA. Karolina PASTUSZKO answered that in principle they rely on the applicant`s declaration but in rare cases when there is a doubt, the Polish eCA ask the applicant for additional information. Hence, it's more a case by case approach.

Another NHD commented that they require from the applicant to submit the full composition of the SBP also when both products are manufactured by the same company. Actually they were confronted with the situation where the compositions of both products were not identical, despite the declaration of the SBP applicant.

Karolina thanked for all the comments and concluded that it is important that NHDs as first contact point provide support for the prospective applicants and highlight for them possible problems before the submission takes place.

3.4 What consumers know about biocides: Results from a survey in Germany

Christiane STARK (scientific officer at the German Environment Agency - UBA) presented the results of the survey conducted in Germany on what consumers know about biocides. The aim of the project was to learn about the interaction between consumers and biocidal products and to learn what was needed for successful risk management of biocidal products especially from the perspective of the consumers. Their focus was on risk mitigation measures because there are often pre-conditions for the authorization of biocidal products.

She explained that biocides are a highly diverse group of chemicals and for risk assessment there was quite a lot to consider, for example that many biocidal products are used by non-professional users in their homes, so they tend to have a lower risk awareness as they don't have a routine handling such products. One reoccurring question was what are suitable risk mitigation measures for consumers? Many risk mitigation measures (RMM) are rather long and detailed using technical terms. On the other hand, consumers have limited resources and/or motivation and limited prior experience. There are several steps that need to be fulfilled to protect the environment starting from being aware of potential risks connected with the use of a biocidal product such as to pay attention to the label and instructions. Secondly, even if the consumer is aware of the risk, they might still misunderstand the meaning or personal relevance of the instruction, they might not be motivated to protect the environment because of the inconvenience of lack of perceived responsibility.

The survey objectives were to find out how familiar consumers were with biocidal products and their potential risks and secondly to assess how comprehensive consumers think specific user instructions are and if certain variations of these instructions influence the rating of the consumers. The data was collected in Germany by online survey in 2022, the participants were recruited with the support of a market research company. The participants were confronted with 12 fictional situations e.g. ant infestation and a fictional biocidal product as solution for their problem. They were asked how comprehensible the instructions and RMM on the product were. Besides comprehensibility there were also other important parameters to be assessed such as the practicability and the motivation to implement the RMM (protection motivation).

The speaker then highlighted the results: the most frequent spontaneous associations participants had with the term biocidal product was first "poison", second "agriculture" and third "pest control". Also, a substantial part of consumers admitted they didn't know what biocidal products are. Some word associations revealed meaning misconceptions such as: "environmentally friendly", "not chemical", or "natural". Those wrongful associations summed up to 50% of the responses.

On the perceived responsibility for safe use approximately 75% of participants agreed that it

was their responsibility not to harm the environment with BP but around 60% said that it was the responsibility of the manufacturer to produce BP in a way that it does not harm the environment. Interestingly 20% believed that commercially available BPs are safe for the environment because they have been authorised by authorities. This indicates that consumers may underestimate the potential risk of BP.

Regarding the comprehensibility of basic instructions, around 70% of respondents stated that the instructions are rather or very comprehensible but on the other hand a substantial part said that they do not find the instructions comprehensible. Approximately 25% do not understand the instructions.

Summarizing, the speaker concluded that a substantial part of consumers was not aware about potential risks associated with the use of biocides, 30% indicated low comprehensibility and practicability of instructions. Subtle variations in phrasing seemed to have negligible impacts on the comprehensibility and practicability of RMM. Christiane recommended using examples for ambiguous terms and locations, avoiding technical (e.g. spot application), not fully defined terms (e.g. regularly) and restrictions that involve external factors like rain or wind. Limiting the frequency of BP application and the extent of some uses would lower the protection motivation and would reduce likelihood of following such instructions by consumers.

the speaker expressed the wish to continue this work to get more broad conclusions and more sound scientific databases to decide on the suitability of risk mitigation measures for the authorization process.

Discussion

The Commission commented that they are aware of the finding of the survey as they were also presented at the "Seminar on best practices in national authorisation procedures" held on 15 February 2024 by the Commission. As the results are indeed a bit worrying, the Commission is reflecting on the proper actions like revision of the list of frequently used sentences for RMM.

CEFIC mentioned a similar project carried out by Belgium[3] and the following campaigns.

One NHD commented that it's crucial that the authorities communicate on this topic and raise the awareness of the consumers from the very early age.

Closing of the BPR Workshop

The Chair concluded thanking the participants for their active participation and discussions and outlined that there were no action points at the end of the meeting. She invited the participants to reply to the satisfaction survey which would be sent after the meeting and closed the BPR Workshop, until the next one foreseen for autumn 2024, on 7 November.

The conclusions of the day took form of the SliDo quiz prepared by ECHA (A2) containing the questions related to the presentations held during the day. **Malgorzata SZKLAREK** (ECHA) described the rules and run the quiz.

The chair then thanked everyone for their contribution and closed the meeting.

[33] Presented at the HelpNet workshop on 16 November 2023 under agenda point 3.2 see the Minutes

Annex I – Agenda of the BPR Workshop

BPR Workshop

Venue: ECHA, Sisu Conference Centre

Chair: Elena BIGI

BPR Workshop	
1. Opening the BPR Workshop	
09:30	1.1 Opening by the Chair (ECHA, Elena BIGI)
09:35	1.2 Follow-up of action points from the BPR Workshop in November 2023
09:40	1.3 Approval of the draft agenda Declaration of conflict of interest with any of the agenda items
2. Updates from the European Commission and ECHA	
09:45	2.1 Updates from the European Commission (DG SANTE, Ligia NEGULICI)
10:15	2.2 Updates from the biocidal units (ECHA, Javier SANCHEZ SAEZ)
10:35	2.3 Updates from the Legal Affairs unit (ECHA, Camilla BUCHANAN)
Coffee break (10:55-11:15)	
3. Topics proposed by HelpNet members and observers	
11:15	3.1 Updates on Summary of the Product Characteristics (SPC) integration into IUCLID (ECHA, Roberto GILIOLI)
12:00	3.2 SPC for Biocidal Product Family (ECHA, Ruben GONZALEZ VIDA)
Lunch break (12:20-13:20)	
13:20	3.3 Challenges with mutual recognition and same biocidal products application (Poland, The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Karolina PASTUSZKO)
13:50	3.4 What consumers know about biocides: Results from a survey in Germany (Germany, Federal Environment Agency, Christiane STARK)
14:10	Quiz (ECHA)
14:25	**Conclusions of the day**
14:30	End of the third day meeting
Sandwich and coffee (14:30-14:45)	

Annex II - List of participants

Country	Name, surname
Austria	Natalie Christine HOFMANN
Belgium	Kristof CLAES
Croatia	Ivana VRHOVAC FILIPOVIC
Czech Republic	Aneta KULHAWIKOVA
Denmark	Lone KÆRGAARD
Estonia	Riina LAHNE
	Anu Meriste (remote)
Finland	Hannu MATTILA
Germany	Juliana Sophie REY
	Christiane STARK
Hungary	János BACSÓ
Ireland	Louise PIERCE (remote)
Italy	Raffaella PERRONE
Latvia	Evija PORIKE
Lithuania	Evelina BARONIENE
Luxembourg	Jeff ZIGRAND(remote)
Netherlands	Evan BEIJ (remote)
Poland	Karolina PASTUSZKO
	Agnieszka BARANOWSKA-MOREK (remote)
Romania	Mihaela-Simona DRĂGOIU
Slovak Republic	Jadža PORUBIAKOVÁ
	Maria SKULTETYOVA (remote)
Slovenia	Marta PAVLIČ ČUK
Spain	David CANO GOMEZ
Sweden	Åsa Almkvist (remote)
	Theresa HOL (remote)

European Commission

DG	Name, surname
DG SANTE	Ligia NEGULICI

Third Country observers

Country	Name, surname
Montenegro	Suzana OTASEVIC
	Tatjana MUJIČIĆ
Serbia	Jelena GRUJIC
	Biljana MILENKOVIC (remote)
Türkiye	Okan KUMCU

Industry observers

Organisation	Name, surname
A.I.S.E.	Elodie Cazelle (remote)
Cefic	Jules BOSSERT
	Lars SCHMAL

ECHA staff

Unit[4]	Name, surname
A2	Anna Liisa PIKKARAINEN
	Laura CHAMAK
	Malgorzata SZKLAREK
	Roxana BROASCA
	Ruben GONZALEZ
E2	Camilla BUCHANAN
D2	Javier SANCHEZ SAEZ
	Roberto GILIOLI
I2	Slav KISSIOV
R2	Konstantinos ANAGNOSTAKIS
	Marko POPOVIC
	Teuvo HONKAKUNNAS

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