HelpNet BPR Workshop (WebEx session)

19 May 2022

Summary of discussions

The HelpNet BPR Workshop, organised for the Biocidal Product Regulation (BPR) members and observers of HelpNet, took place on 19 May 2022 by web conference. This document summarises the topics discussed[1] during the workshop (Annex I) and the results of the polls (Annex II).

Opening of the BPR Workshop

The Chair of the HelpNet, Erwin ANNYS (ECHA) opened the BPR Workshop and welcomed the representatives of the national helpdesks, observers from potential candidate and third countries and industry attending the event (see Annex III to these minutes). He expressed his hopes that, in autumn 2022, HelpNet events will be held in Helsinki face to face.

The action points from the previous BPR Workshop in November 2021[2] were all closed. The Chair introduced the agenda of the day, which was adopted without further comments.

1. Updates from the European Commission and ECHA

1.1 Update from the European Commission

Ligia NEGULICI (European Commission, DG SANTE) gave an update on the implementation of the Biocidal Products Regulation (BPR) since the previous BPR Workshop in November 2021 (at the HelpNet 16), informing the participants about new developments, legislative amendments, discussions and agreements at the competent authorities (CA) meetings. The presentation covered the following:

- **update on topics related to COVID-19 and the impact on biocides**

The Commission highlighted that the impact of the pandemic on the biocidal sector is lower than it used to be but still visible. Since the last HelpNet BPR Workshop, two Member States and the United Kingdom (in respect of Northern Ireland), granted temporary permits for disinfectants (PTs 1, 2, 4).

Since HelpNet 16, two Member States issued emergency permits for a preservative product for the treatment of aircraft fuel. For the time being, almost all Member States granted such permits, as there is only one product available on the market for this use and more permits are expected to be granted in the future.

[1] Note that the text of the Biocidal Products Regulation is the only authentic legal reference and that the summary in this document do not constitute legal advice. For further advice, contact your national helpdesk: https://echa.europa.eu/support/helpdesks/
[2] BPR Workshop (5 November 2021): https://echa.europa.eu/about-us/partners-and-networks/helpnet/2021

- **requirements for packaging size and labelling on dispensers and refilled containers for hand disinfectants[3]**

Ligia NEGULICI informed about the agreement that has been reached at the Coordination Group (CG) and CA meetings, where it was concluded that hand disinfectants distributed in large packaging volumes should be used with a dispensing pump/system. Such use should be included in the risk assessment and explicitly stated in the summary of product characteristics (SPC). As information should be available to the user also on dispensers and/or refilled containers, the minimum labelling requirements for dispensers and or/refilled containers include:

- authorisation number;
- trade name of biocidal product;
- identity and concentration of each active substance;
- directions for use; and
- information triggered by the CLP Regulation.

The maximum packaging size to be marketed without a dispenser should be decided by the evaluating competent authority as a result of the risk assessment.

- **Implementing Decision (EU) 2022/146 determining whether a product containing ADBAC/BKC is a biocidal product or not[4]**

In its decision, the Commission concluded that the product, although marketed by its manufacturer as a cleaning product, fulfils the definition of biocidal product (PT 2) as it is intended to prevent and control the growth of unwanted algae. One element of the rationale behind this decision is based on the Court Judgment in case C-592/18 Darie[5], where it was clarified that detergents are not excluded from the scope of Regulation (EU) No 528/2012. The Commission also highlighted that when assessing whether a product is a biocidal product or not, all the available information – provided by the manufacturer, by distributors and at points of sale – should be considered. In this particular case, it was indeed the information provided to consumers by a distributor and an online point of sale that supported a biocidal claim on it (i.e. direct effect on algae on surfaces).

When deciding on the nature of the product, the concentration of active substances may also give an indication that the product is placed on the market with a biocidal intent. The concentration of ADBC/BKC in the assessed product was similar to the one in algae-removing biocidal products authorised in one Member State.

- **changes in mutual recognition (MR) procedures (possible amendment of Regulation (EU) 492/2014)**

The Commission informed that inconsistencies regarding the Renewal Regulation and other regulations related to the period of grace, were brought to their attention. As a result, the Renewal Regulation is likely to be amended.

In relation to the MR procedures, it was also concluded at the CA meetings that in case of non-authorisation of the product by the reference Member State (refMS) or decisions related to major/minor change applications subject to mutual recognition in parallel, refMS may still raise a referral to the Coordination Group. When a non-authorisation decision is issued by refMS, the

[3] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/a2828a64-64ba-4e79-bbde-6d5a12129c1b/details
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022D0146
[5] https://curia.europa.eu/juris/document/document.jsf;jsessionid=024D636F414B78B88BABC739738B2018?text=&docid=221808&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=14634525

concerned Member States have the right to comment on the conclusions of the assessment report or on the revised SPC. Relevant operating procedure of the Coordination Group have been updated[6] to reflect these conclusions.

- **use of active substance trivial/common name**

The Commission reported that at the CA meetings the possibility to include a trivial name of the substance in the SPC and the label of the product was discussed. It was concluded that it is achievable under certain conditions:

- Common names should be set at active substance approval and should also be indicated in the Implementing Regulation approving the active substance and on ECHA's website (substance infocard).
- Clear link between systematic name and common name should be publicly available (and also linked in Annex VI to CLP).

In practice, common names should be decided on a case-by-case basis, with the acceptance of industry and competent authorities also involving the BPC Working Group on analytical methods and physio-chemical properties.

- **technical assistance to Member States**

As a follow up to the Report on the implementation of the BPR[7], the Commission sent letters to Ministers responsible for implementing the BPR, offering financial support to Member States in the area of biocides and plant protection products through grants that Member States may apply, starting most likely from the beginning of 2023. On 3 June 2022, the Commission together with ECHA and EFSA organised a workshop to further discuss this topic with Member States.

- **innovations in the biocides sector**

As the Report on implementation of the BPR indicates that very little innovation appears in the biocides sector, the Commission acknowledged that further innovation is required.

The actions taken by the Commission and ECHA in this respect included the development of a new guidance (*Guidance on the assessment of alternatives* and *Guidance to assess efficacy of rodent traps*) but also – under Horizon 2020 – the opportunity was given to apply for the founding of the EU research programmes that were available for the development of alternatives to biocides used at the farm level.

Discussion

The Chair thanked the presenter for the insightful and useful presentation and noted that lack of innovation is of great importance, highlighted also by Cefic and A.I.S.E in their report (see agenda item 2.1).

The Chair asked whether from the Commission's point of view, granting more provisional authorisation for biocidal products containing new active substances under Article 55 (2), would help innovation or whether this would be a global issue, not just EU-related.

The presenter responded that indeed Article 55 (2) allows Member States to grant such authorisations, but the industry is not keen on using it, as not many applications have been received so far. The lack of innovation may be caused by many factors including:

[6] https://circabc.europa.eu/w/browse/72608118-7e73-4ee0-aecf-2cbbcc52b29f
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0287

- high regulatory cost;
- long timelines for active substance approvals;
- small size of biocidal market compared to other chemicals, market fragmentation and high proportion of SMEs;
- limited return on investment;
- slow progress with the Review Programme: as biocidal products can be still placed on the market under more lenient national regulations, companies are not stimulated to introduce new products.

The Chair made a reference to the recently published report summarising the activities of the national helpdesks in 20218. Although the number of BPR, CLP and REACH questions went down compared to the first COVID-19 year, the 55 000 questions handled by the national helpdesks and the 12 000 questions covered by ECHA are still the second highest number in the history of HelpNet.

Later during the workshop, one question was posted by chat related to the date when new requirements for packaging size and labelling on dispensers and refilled containers for hand disinfectants becomes applicable to the applications. The speaker explained that new requirements are most probably not applicable to the ongoing applications and mentioned that the agreed cut-off period for applicability of new guidance for biocidal product is two years since the agreement and six months for the substance approval[9].

1.2 Q&A search project (outline and feedback) and updates on the BPR Q&As and FAQs

Roxana BROASCA (ECHA) presented the new Q&A search tool and Małgorzata SZKLAREK (ECHA) presented the outcome of the revision of the regulatory BPR Q&As.

After a brief outline of the new Q&As management and planned improvements in the involvement of NHDs, the new Q&A search tool was presented. The tool was developed by the Regulatory Support and iTEX teams as an improvement of the searchability of the Q&As in response to the feedback received from customers and NHDs. Roxana BROASCA demonstrated how the tool can be used in various ways to search Q&As – by topic/scope, by ID and by keyword. The tool still needs to be finalised and further comments are welcome, before the go live foreseen for Q3/Q4 2022.

A poll was launched to gather the first impressions from the participants.

Roxana BROASCA also addressed two questions received from the Dutch correspondent about the Q&A search tool, one on the filter options that can indeed apply simultaneously, as demonstrated live and the other, on whether the Q&As will be migrated to the new tool. Roxana confirmed that all the Q&As will be migrated to the new tool and they will keep their ID numbers and same links.

Małgorzata SZKLAREK (ECHA) introduced the outcome of the revision of the regulatory Q&As, which was initiated by ECHA last year and covered 69 regulatory Q&As (including FAQs). Q&As related to R4BP 3 and fees were not included in the revision. NHDs were consulted on the

[8] Annual reports of national helpdesks and ECHA are available at: https://echa.europa.eu/about-us/partners-and-networks/helpnet/2021

[9] The Commission informed after the meeting that the applicability of this agreement has not been discussed and agreed with Member States and that this and similar agreements are not to be considered new formal guidance, but rather as clarifications.

revision of five FAQs.

A new FAQ (Can the term 'natural'(or similar) be a part of the trade name of a biocidal product, even when the trade name is a registered trademark?)[10] developed this year was also presented. Consultation with the Commission took place back in 2015 and included a scenario where trading of the product is a registered trademark. The final version (re-drafted by ECHA, agreed with the originator of the question and aligned with the result of the discussion that took place at the CA meeting on a similar topic) was considered approved by NHDs as no comments were received during the consultation.

Finally, the speaker mentioned the ongoing revision of Q&A 1020 that has not been finalised yet and the possibility future developments of new Q&As most likely in relation to Article 95 listing and data protection under Article 95 (5).

Discussion

The Chair commented on the outcome of the poll 2 (see Annex II). He explained that the majority of NHDs indicated that they use Q&As to reply to the questions only "sometimes" or "rarely". This is most likely linked to the distinction of competences among ECHA and NHDs and the difference in topics addressed by ECHA and by NHDs.

One question was received by the HelpNet Secretariat by email. The question was related to information on fees being difficult to find on ECHA's website. The question raised the lack of a Q&A section on fees and a link to the Fee Regulation on Q&As on ECHA's website. Poor availability of the information on the fee reduction for SMEs was also mentioned.

ECHA thanked for the suggestion and welcomed all new FAQ proposals that will proceed in accordance with the established procedure. Also, it was mentioned that Q&As related to fees are published on ECHA's website under the topic "R4BP 3" scope "Invoicing and payments". They include Q&A ID 0760 "Where can I find an overview of the fees?" that direct to the Fee Regulation and Q&A ID 0917 "How do I indicate my company size?" that explains who is entitled to reduced fees and when is the reduction possible. It was highlighted that the new search tool should make this information more easily accessible for SMEs.

2. Topics proposed by national helpdesks and observers

2.1 Biocides for Europe and A.I.S.E. report on the implementation of the BPR

Boris VAN BERLO (Cefic) presented the report on the implementation of the BPR elaborated by Biocides for Europe (a sector group of Cefic) and A.I.S.E.

The report[11] is based on a survey and interviews with companies operating on the biocidal market and it has been commissioned to the consultancy company ERM[12] with the support of Fieldfisher[13]. Feedback was received from around 100 companies (approximately 50 % SMEs) representing all actors in the supply chain. Seven key concerns interlinked with each other were identified based on the surveys:

[10] https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1899
[11] The report can be found on the Biocides for Europe and A.I.S.E. websites.
[12] https://www.erm.com/
[13] https://www.fieldfisher.com/en/locations/belgium

1. The complexity of the BPR, intensified by the co-existence of the national regulatory regimes (in parallel to the BPR) and the constant development of new guidance documents. The creation of a central document, capturing previous decisions related to borderline and scope issues (similar to the old manual of decisions) and an overview document of all guidance documents relevant for dossier preparation (separately for active substance dossiers and biocidal products), would help not only the industry but also the Member States.

2. Moving goals posts - constantly developing new guidance and updating existing ones is linked to delays in active substance approvals and biocidal product authorisation. The speaker highlighted that the application of new Guidance to already submitted applications is very problematic and is partially responsible for delays. The recommendation is not to apply new guidance to the ongoing evaluations and analyse and implement best practice from other regulations (e.g. Plant Protection Products Regulation, REACH).

Non-harmonisation - caused by the complexity of the BPR, the co-existence of the national regulatory regimes and deviations from common rules through e.g. disagreements/referrals during the mutual recognition. This could be solved by increasing the expertise in all Member States (which would allow Member States to rely on each other's work and not to duplicate the assessment), and by analysing the reasons for disagreements or referrals to identify potential lessons learnt to improve harmonisation.

3. Delays – especially in the context of the Review Programme (RP), where 58 % of the RP still needs to be completed. The main solution would be to increase the level of resources in Member States and support from ECHA in an equal spread of the workload among Member States. Better communication between evaluating competent authorities and applicants was also highlighted.

4. Lack of a level playing field - due to complexity, delays, co-existence of the BPD rules and the BPR, allowing Member States to deviate from harmonised decisions and follow national law instead. Focusing on the finalisation of the review programme would enhance the level playing field.

5. Lack of predictability - as a result of the factors mentioned before, such as the complexity, delays, lack of harmonisation and moving goals posts.

6. Lack of innovation – caused by all the factors above complemented by the hazard-based approach and the ambition to achieve "zero risk" scenario, which prevents valuable products to enter the market. Limited or late return of investment in R&D and regulatory costs are also considered by companies as barriers to innovation.

It was highlighted that there is no "one-fits-all" solution, and all the factors and the key issues mentioned in the report are linked to each other.

Discussion

The Chair commented on the perception of the BPR by industry and the concerns regarding the implementation of the BPR and acknowledged that the ECHA Helpdesk shares some of the industry observations. He then opened the floor for questions.

One participant expressed sympathy for industry and asked what actions can be taken through the HelpNet and if the presentation was delivered in other meetings.

Boris VAN BERLO responded that a similar presentation was given at the CA meeting and

highlighted the need for joint cooperation of all parties (Commission, ECHA, Member States) in improving the situation.

Although the helpdesks' involvement may be perceived as limited, the speaker emphasised that helpdesks in general can quickly identify emerging issues where support is lacking, or clarification is needed and flag such issues also to Cefic and A.I.S.E. Both organisations can spread the answers to such re-occurring questions to their members through their communication channels. It could be useful for the daily helpdesks' work, reducing the number of the incoming enquiries.

The Chair welcomed this proposal and indicated that the HelpNet Secretariat will discuss within the network of NHDs how this cooperation could be organised in practice and further liaise with Cefic.

ECHA (Chiara PECORINI) added that some discussions with Biocides for Europe already took place and that ECHA can contribute to the improvement of the situation e.g. in the area of guidance documents and the BPC Work Programme. She assured that ECHA will follow up with Biocides for Europe and A.I.S.E.

Conclusions of the day

The Chair gave a short wrap-up of the meeting, thanking participants and presenters for their active and valuable contributions to the meeting. He then informed about the action point (HelpNet to follow up with A.I.S.E. and Cefic on recurring questions) and the usual satisfaction survey which followed the meeting.

The Chair mentioned that the survey will include questions related to the HelpNet events in the autumn. To avoid the overlap of the HelpNet BPR Workshop with the CA meeting on 6 October, the Secretariat is looking into the possibility to change the dates of HelpNet 17 events from the beginning of October to 25-27 October. He expressed his wishes to meet all the BPR members and observers in autumn, at the 17th Steering Group meeting, the social event and the BPR Workshop taking place on 26 and 27 October 2022.

Annex I – Agenda of the BPR Workshop

Opening by Erwin Annys, the Chair of HelpNet

Session 1 - Updates from the European Commission and ECHA

1.1 Update from the European Commission (European Commission, Ligia NEGULICI)

1.2 Q&A search project (outline and feedback) and updates on the BPR Q&As and FAQs (ECHA, Roxana BROASCA, Małgorzata SZKLAREK)

Session 2 - Topics proposed by national helpdesks and observers

2.1 Biocides for Europe and A.I.S.E. report on the implementation of the BPR (Cefic, Boris VAN BERLO)

Conclusions of the day

Closing the BPR Workshop

Annex II – Results of the polls

Agenda point 1.2 Q&A search project (outline and feedback) and updates on the BPR Q&As and FAQs

1. What do you think about the new Q&A tool overall?

A.I like it!	**10/31**
B.I don't like it, could be better.	**0/31**
C.I am not sure yet	**8/31**
D.I have some suggestions	**0/31**
No Answer	**13/31**

If you have any suggestions, please add them here:

No Answer	**31/31**

2. How often do you refer to regulatory Q&As in your replies?

A.Quite often	**0/31**
B.Sometimes	**7/31**
C.Rarely	**6/31**
D.Never	**3/31**
No Answer	**15/31**

3.Which scope of the regulatory Q&As do you find the most useful?

A.Active substance suppliers	**3/31**
B.BPR General	**5/31**
C.Data Sharing	**2/31**
D.In-situ generated active substances	**10/31**
E.Parallel Trade	**0/31**
F.Review programme	**2/31**
G.Simplified authorisation	**1/31**
H.Treated articles	**7/31**
No Answer	**18/31**

Closing the BPR Workshop

4.Would you be able to attend the BPR and HelpNet workshop on 25-27 October (27 would be CLP and BPR)?

A.Yes	**19/21**
B.No	**0/21**
No Answer	**2/21**

Will you attend face to face?

A.Yes	**9/21**
B.No	**9/21**
No Answer	**3/21**

Annex III - List of participants

Country	Name, surname
Austria	Jéromè COLSON
Croatia	Ivana VRHOVAC FILIPOVIC
Croatia	Tajana KOVAČEVIĆ*
Denmark	Helle HUSUM
Denmark	Lone KÆRGAARD
Estonia	Riina LAHNE
Finland	Hannu MATTILA
Germany	Juliana REY
Hungary	Henrietta SZABÓ
Ireland	Louise PIERCE
Ireland	Mervyn PARR
Latvia	Evija PORIKE
Luxembourg	Jeff ZIGRAND
Netherlands	Evan BEIJ
Netherlands	Peter VAN IERSEL
Norway	Jorid FRYDENLUND
Poland	Łukasz BELKIEWICZ
Romania	Simona DRĂGOIU
Slovak Republic	Jana CHMELIKOVA
Slovak Republic	Maria SKULTETYOVA
Slovak Republic	Marta PAVLIČ ČUK
Sweden	Anneli RUDSTRÖM

European Commission

DG	Name, surname
DG SANTE	Ligia NEGULICI

Third Country observers

Country	Name, surname
Switzerland	Silvia NANNI

Industry observers

Organisation	Name, surname
Biocides for Europe - Cefic	Boris VAN BERLO
EDANA	Luminița BARBU
Fecc	Simina DREVE

ECHA staff

Unit	Name, surname
A2	Amandine JOMIER
	Elena BIGI
	Erwin ANNYS
	Evelyne FRAUMAN
	Joose KORHONEN
	Julia SIERRA
	Malgorzata SZKLAREK
	Roxana BROASCA
	Ruben GONZALEZ VIDA
	Viorica NAGHY
D2	Chiara PECORINI
R3	Daniel NYGARD