HelpNet BPR Workshop: summary of discussions

Time: Tuesday 29 November 2016, 10:30 – 14:00
Place: Web Conference (remote participants)
        European Chemicals Agency, K323 (ECHA participants)

The HelpNet BPR Workshop was organised in a Web Conference format via the WebEx tool. This document summarises the ideas discussed during the BPR Workshop and the agreed conclusions.

1. Opening of the workshop

The Chair, Pedro ROSELLO VILARROIG (ECHA), welcomed the participants. He went through the main functions of the WebEx tool, referring to ECHA’s WebEx instructions provided to the participants, gave an update on the status of the action points from the previous HelpNet BPR workshop in April 2016 and presented the draft agenda of the session. The agenda was adopted with no further comments.

1.1 Update from ECHA, Biocides Assessment Unit

Jan WEBER (Biocides Assessment Unit, ECHA) presented the recent and upcoming developments of ECHA’s biocides IT tools, particularly R4BP 3.8 and SPC Editor 2.0, covering the period since the BPR IT tools training in April 2016.

R4BP version 3.8 was released in October 2016. It includes a number of new processes and improvements under Union Authorisation; Same Biocidal Product; family SPC. More information is available in the R4BP Submission Manuals and in the version 3.8 release note.

SPC editor 2.0 includes new features under family SPC structure and the structure of information. The presenter highlighted the information on data migration within the product families, issues that applicants may face (incomplete SPCs, SPC data duplication, migration finalising steps) and that NHDs may need to clarify to their customers.

Upcoming developments in ECHA’s biocides IT tools include addition of remaining regulatory processes, adding more flexibility to the system (e.g. bulk actions and transfer of cases), improved usability and communication features; integration of IUCLID and dissemination; the possibility to request data correction directly in R4BP.

1.2 Update from the European Commission

Martinus NAGTZAAM from the European Commission (COM), DG Health and Food Safety (DG SANTE), provided an update on the latest Biocides related developments.

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1 The text of the BPR is the only authentic legal reference and that this workshop summary does not constitute legal advice. For further advice, contact your national BPR helpdesk.
2 The names of the participants attending the BPR Workshop are listed in Annex I of this summary.
3 R4BP Submission Manuals are available on ECHA website at: https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals
4 The summary follows the initial Agenda, available in Annex II of this summary, and does not reflect the changes regarding the order of presentations.
The revised process for BPR questions in HelpEx, with a focus on the scope issues, was discussed in the BPR competent authorities (CAs) meeting in November 2016. The CAs were asked to submit their comments in writing.

COM received 22 new applications for in-situ generated active substances in Q3-Q4 2016. The number of Union Authorisation (UA) applications is better than expected (14 in 2015, 25 in 2016, 14 on-going pre-submissions with applications expected by 1 February 2017). COM is working on establishing the relevant administrative procedures. COM expects that the first UAs will be granted in late 2017 – early 2018.

COM expects to have the decisions on the renewal of anticoagulant rodenticides adopted in Q1 2017. Biocidal product authorisation renewal will re-start by the end of February 2017 with the decision expected by May 2017.

In relation to the treated articles, COM highlighted the upcoming deadline of 1 March 2017, after which only articles treated with or intentionally incorporating active substances approved or under evaluation in the EU will be allowed on the EU market. COM carries out communication campaign to all third countries’ delegations and missions to the EU and to World Trade Organisation (WTO) contact points.

The Biocides Enforcement Group (BEG) will become a subgroup of the ECHA’s enforcement Forum. This decision was endorsed by the CA meeting and by COM.

The updated approach to the setting of minimal risk levels (MRLs) will consider exposure to the same substance from multiple resources, default values, processed and composite food. The interim approach is being revised to consider the situations where significant levels of residues in food would arise from the envisaged use of the biocide.

The possible revision of the Fee regulation or revision of its implementation (i.e. payment by instalments) is on COM’s agenda. So far, ECORYS analytic study has been published; industry’s position paper has been submitted; the topic was included into the agenda of the CA meeting for discussion; the impact of the Fee regulation on SMEs / in situ has been considered.

Endocrine disruptors were discussed in several BPR CA expert group meetings (draft minutes are published on DG SANTE’s website; written comments are published on CIRCABC). The Guidance on endocrine disruptors will be developed jointly by ECHA and EFSA. A scoping paper with an outline of the guidance and foreseen consultations will be presented by the end of 2016. Draft guidance is foreseen to be ready for consultation by the end of Q2 2017.

1.3. Update from the European Commission’s Biocides Enforcement Group (BEG)

Maciej BARANSKI (Forum Secretariat, ECHA) presented an update from the European Commission’s Biocides Enforcement Group (BEG).

In summer 2016, Forum, BEG and BPR CAs were invited to give their views on the three ways of organising BPR enforcement coordination: 1) BPR enforcement coordination fully integrated in the Forum; 2) BPR enforcement coordination handled by a subgroup of the Forum; 3) BEG remaining as a separate entity (chaired by COM). As a result of this consultation, the majority of the BEG and Forum members clearly favoured option 2 (BPR Subgroup of the Forum). COM and BPR CAs endorsed this decision in September 2016.

The objective of the newly established Forum’s BPR Subgroup is the implementation and enforcement of BPR legislation including coordination and cooperation with MS and stakeholders. The subgroup will be a sub-structure of the Forum and can utilise its existing working procedures. Close coordination with the Forum and cross-reporting on activities will be ensured.
The formal discussion of the BPR Subgroup’s work programme will start in March 2017 during its first meeting. The Forum’s Rules of procedure will be updated accordingly.

1.4. Update from ECHA - Guidance development on BPR

Johan NOUWEN (HoU Support, Forum and HelpNet Secretariat, ECHA) presented an update on recent BPR guidance developments.

The presentation covered the structure of the BPR guidance. It gave an overview of the guidance development, consultation, approval and publication process, and explained the role of the Partner Expert Groups (PEGs), biocides CAs, and ECHA in it. The presentation also provided an update on guidance documents in different stages: already published, under consultation or foreseen to undergo consultation. Estimated publication time windows until the end of 2017 were given.

1.5. Questions and Answers

- **In the new version of R4BP, who will be able to make the direct data correction (applicants, ECHA, MSCAs) and how would the process be implemented?**

ECHA is in the very early stages of the analysis and no decisions have been taken yet. If the data needs to be verified by an MSCA or ECHA, this step would definitely be foreseen in the process.

- **The COM mentions issues with BPR Union applications and similar uses. Is it expected that there will be guidance developed to solve these issues? Is further guidance on the creation of Biocidal Product Family (BPF) structure expected?**

COM is currently working on the administrative procedures. More information was provided to the participants after the meeting.

- **When will the guidance on estimating transfer of biocidal active substances into foods-professional uses be available?**

While the guidance development is in the remit of ECHA, the issue is part of the ongoing consultation with the CAs. The timeframe for the guidance development was also covered in agenda point 1.4.

- **Classification is no longer part of the eSPC. Will ECHA disseminate the C&L information and what sources will it be taken from?**

C&L information is listed in the assessment report. Therefore it is no longer required in the SPC (the SPC public by default). Further clarification is needed from the ECHA dissemination experts on whether the data in the assessment report is considered non-confidential and can be

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5 The presentation is available on S-CIRCABC at: [https://webgate.ec.europa.eu/echa-scircabc/w/browse/10e61ad5-ffd6-4926-9cf8-82aa49a40dbd](https://webgate.ec.europa.eu/echa-scircabc/w/browse/10e61ad5-ffd6-4926-9cf8-82aa49a40dbd)

6 Post-meeting note provided by COM: Relevant reference in the Same Biocidal Products Regulation:

"Article 4b - Guidance on handling applications for authorisation of same products
1. The Agency shall, after consulting the Member States, the Commission and interested parties, draw up guidelines on the details related to the handling of applications covered by this Regulation.
2. Where necessary, those guidelines shall be updated taking into account the contributions from Member States and interested parties on its implementation as well as scientific and technical progress"
2.1. Presentation of the Swedish Biocides Helpdesk

Leif BENGTSSON (SE) presented the Swedish Biocides Helpdesk and in particular the way they work in supporting their customers. The presentation was aimed at sharing the practices of the Swedish HD with the HelpNet peers and ECHA.

The presentation covered the structure and main tasks of the helpdesk; introduced the information service ‘Ask the Swedish Chemicals Agency’; the numbers and main topics of the questions they receive on biocides and the types of customers to whom they are addressed. He also presented other activities of the Swedish HD in 2016 and their plans for 2017.

2.2. Questions and Answers

- What are the organisational arrangements for the phone service provided by the Swedish HD? Have the HD staff received a specialised training?

The HD staff use separate offices and have received customer service training at the launch of the phone service.

- Does the HD act as the first point of contact to the national enforcement authorities, for example for trainings or clarifications?

In Sweden Helpdesk is separated from the enforcement activities.

- Does the Swedish HD find it challenging to define its role vis-à-vis the role of a consultant?

This relationship can be challenging sometimes and the issue is relevant to many HDs as well as to ECHA. The helpdesks continue to encourage the consultants to develop their own skills and use the resources available at the national and the EU levels. At the same time, the helpdesks and ECHA continue to provide an advisory service to the consultants as well as to the companies and the public.

3.1. National perspective - possible improvements of HelpEx

Dr. Sylvia GASSEL (DE) presented their national perspective on possible improvements of HelpEx. She covered the experience of the German Helpdesk in using HelpEx, its search function, commented on the time requirements and the FAQ process.

Germany has posted 19 questions in HelpEx as ‘originator’ and provided 30 comments to the questions posted by other NHDs. The main issue are the scope questions, i.e. differentiation between product-types, biocidal products and treated articles and questions regarding legal

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Post-meeting note provided by ECHA’s Biocides Assessment Unit (D1): There might be self-classification of the applicant in the IUCLID dossier/assessment report but ECHA does not look at the classification of biocidal products. Anyway, it was agreed by the CA meeting to not have classification information in the SPC. ECHA only implements what has been decided by COM and/or the CA meeting. ECHA’s description of the new family SPC structure is available at:


References to the relevant CA meeting documents can be found here:

1) CA meeting document on the Note for Guidance on the BPF concept Implementation (CA-Nov14-Doc.5.8-Final.rev1): https://circabc.europa.eu/w/browse/c309ae58-bdd7-421d-a678-8d8ac361d4e0
2) CA meeting document on the SPC structure: CA-May15-Doc.4.6.a-Final: https://circabc.europa.eu/w/browse/9193f037-0443-4232-8a13-1949bb1bbcc8
issues and substance identity.

Germany finds HelpEx a good supporting platform for NHDs to share information, agree on harmonised answers, improve the quality of their answers, and bring forward main topics at the EU-level for discussion. They wished to know how the other NHDs are using the tool and encouraged the HelpNet members to be more active in providing feedback to achieve harmonised replies across the EU, e.g. by providing a short comment in support of the proposed opinion. They suggested agreeing on common rules and proposed further improvements, e.g. in the search functions; criteria of FAQ setting; adding keywords to improve the usability of the HelpEx content as a useful knowledgebase.

### 3.2. ECHA perspective – HelpEx database

Nicola TECCE (Regulatory Advice Team, ECHA) presented ECHA’s experiences with the HelpEx BPR questions and its efforts towards harmonised helpdesk questions.

He presented the final version of the CA paper on the ‘revised approach on HelpEx’ highlighting the most recent amendments agreed with COM. Namely, ECHA will notify COM for questions outside ECHA’s remit which may fall in COM’s remit (e.g. scope issues). If needed, COM will directly post on HelpEx the suggested follow-up actions, adding some reasoning (e.g. issue to be raised at the CA meeting for further discussion and agreement; issue to be handled by an Article 3.3 request; etc.). In case the issues can be handled independently by the HelpNet members, no further involvement from COM is expected in HelpEx.

The above mentioned paper was presented at the last CA meeting in November 2016 where no objection were raised by the CA members. COM gave a final window of three weeks to provide written comments to the document (by 15 December 2016). The paper is likely to be endorsed without any further modification at the next CA meeting in March 2017.

The presenter mentioned that ECHA’s Regulatory Advice Team has been following this approach (and the remits reported in the Annex to the paper) since the May 2016 CA meeting. He clarified that ECHA has not received any complaint from the HelpNet members neither from the industry (EU and non-EU). Thus, the procedure suggested in the paper seems to be working properly.

According to the paper, scope questions posted in HelpEx are not considered “FAQ suitable”, as they are not in ECHA’s remit and thus ECHA cannot take the ownership of these questions.

Responding to the issue on the scope questions raised by Germany, the presenter confirmed that ECHA is not in the position to contribute to legal decisions under the BPR. Indeed, while HelpEx is a good tool to facilitate discussion, it is not a tool where legally binding decisions can be taken. ECHA supports the opinion of Germany that it would be useful to gather and make publicly available all the decisions related to BPR scope issues. However, ECHA cannot take ownership of this action, it should rather be COM.

### 3.3. Questions and Answers

Questions of general scope, which formerly were discussed as e-consultations, were agreed to be discussed in HelpEx. These questions include those related to the revoked Manual of Decisions and questions posed by the CAs (in replacement of e-consultations under the BPD). COM informed that there is no intention from their part to re-establish the former Manual of Decisions. COM will contribute to the discussions and information sharing in the appropriate fora. Such a forum is currently the CA meeting where the discussion can take place and the decisions are published in the meeting minutes. ECHA added that it remains the responsibility of the MS

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8 The document is available on S-CIRCABC at: [https://webgate.ec.europa.eu/echa-scircabc/w/browse/26bd7bb6-faae-4771-a736-9d2623212c5f](https://webgate.ec.europa.eu/echa-scircabc/w/browse/26bd7bb6-faae-4771-a736-9d2623212c5f)
initiating the process for bringing a question to the CA meeting.

The practice of the German HD in publishing the relevant Questions and Answers from HelpEx on their national website was supported by several participants.

Technical improvements of the HelpEx tool will be considered by ECHA in 2017. NHDs were invited to provide their suggestions\(^9\) for technical improvements of HelpEx, e.g. improving the usability, friendliness, focusing on the keyword approach.

- To which authority should MSs address the scope issues (CA meeting, COM or the Coordination Group e-consultation)?

ECHA is not in the position to give a specific reply on this question. It will alert COM about the new scope questions.

4. Conclusions and action points

The Chair listed the action points recorded during the session as provided in Annex III.

5. Closure of the HelpNet BPR Workshop

The Chair informed the participants that, due to the upcoming 2018 registration deadline, there will be only one physical HelpNet meeting with regulatory workshops in March 2017. The Chair invited the participants to give feedback on this WebEx session via a Webropol survey with a view to holding more such web conferences instead of physical meetings in the future.

\(^9\) Feedback from NHDs is welcome by the end of February 2017.
Annex I - List of participants

Members of HelpNet

Austria  
Peter Schindler
Michael Weber

Austria  
Ivana Vrhovac Filipovic

Croatia  
Jack Frausing Nielsen

Denmark  
Riina Lahne

Finland  
Hannu Mattila

Germany  
Sylvia Gassel

Iceland  
Elín Ásgeirsdóttir

Ireland  
Patricia Mc Guire

Latvia  
Julija Brovkina
Kristine Krafte

Latvia  
Wayne Giordmaina

Malta  
Eveline Beij

Netherlands  
Suzanne Gordon

Poland  
Renata Kamińska

Romania  
Catalin Gabriel Oprea

Slovenia  
Marta Pavlič Čuk

Spain  
Maria Aranzazu Lopez

Sweden  
Leif Bengtsson

United Kingdom  
Andrew Edwards

Representatives of the European Commission

DG SANTE  
Christophe Kusendila
Martinus Nagtzaam

Observers

Serbia  
Jelena Grujic
Bobana Jakovljevic

Switzerland  
Brunhilde Kolp Buchs
### ECHA

<table>
<thead>
<tr>
<th>Department/Unit</th>
<th>Name</th>
<th>Surname</th>
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<tbody>
<tr>
<td>A2, HoU</td>
<td>Johan</td>
<td>NOUWEN</td>
</tr>
<tr>
<td>A2, Regulatory Advice</td>
<td>Pedro</td>
<td>ROSELLO VILARROIG</td>
</tr>
<tr>
<td>A2, Regulatory Advice</td>
<td>Viorica</td>
<td>NAGHY</td>
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<tr>
<td>A2, Regulatory Advice</td>
<td>Nicola</td>
<td>TECCE</td>
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<tr>
<td>A2, Regulatory Advice</td>
<td>Olena</td>
<td>KRYCHEVSKA</td>
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<tr>
<td>A2, Regulatory Advice</td>
<td>Anna-Lisa</td>
<td>PIKKARAINEN</td>
</tr>
<tr>
<td>A2, Regulatory Advice</td>
<td>Katarina</td>
<td>CENDIC</td>
</tr>
<tr>
<td>A2, Forum Secretariat</td>
<td>Maciej</td>
<td>BARANSKI</td>
</tr>
<tr>
<td>B2, Legal Affairs Units</td>
<td>Theodora</td>
<td>BASMATZI</td>
</tr>
<tr>
<td>B2, Legal Affairs Units</td>
<td>Nicholas</td>
<td>KNIGHT</td>
</tr>
<tr>
<td>D1, Biocides Assessment Unit</td>
<td>Jan</td>
<td>WEBER</td>
</tr>
<tr>
<td>D1, Biocides Assessment Unit</td>
<td>Gabriela</td>
<td>ALDEA</td>
</tr>
<tr>
<td>I2, Submissions Helpdesk</td>
<td>Ruben</td>
<td>GONZALEZ VIDA</td>
</tr>
</tbody>
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### Annex II - Agenda

**HelpNet BPR Workshop - WebEx session**  
29 November 2016

**Chair:** Pedro ROSELLO VILARROIG

#### WebEx Technical Checks (10:30)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration</th>
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<tbody>
<tr>
<td>WebEx technical checks with remote participants</td>
<td>30’</td>
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#### Updates on BPR implementation and enforcement (starting at 11:00)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration</th>
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<tbody>
<tr>
<td>Opening of the BPR WebEx Session</td>
<td>5’</td>
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<tr>
<td>Update from ECHA, Biocides Assessment Unit</td>
<td>15’</td>
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<tr>
<td>Update from the European Commission</td>
<td>15’</td>
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<tr>
<td>Update from Commission’s Biocides Enforcement Group (BEG)</td>
<td>15’</td>
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<tr>
<td>Update from ECHA - Guidance on BPR</td>
<td>20’</td>
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<tr>
<td>Questions and Answers</td>
<td>20’</td>
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#### Contributions from NHDs (starting at 12:30)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration</th>
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<tbody>
<tr>
<td>Swedish Biocides Helpdesk</td>
<td>10’</td>
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<tr>
<td>Questions and Answers</td>
<td>20’</td>
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#### HelpEx (starting at 13:00 – 13:45)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration</th>
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<tbody>
<tr>
<td>National perspective - possible improvements of HelpEx</td>
<td>10’</td>
</tr>
<tr>
<td>ECHA perspective – HelpEx database</td>
<td>10’</td>
</tr>
<tr>
<td>Questions and Answers</td>
<td>20’</td>
</tr>
<tr>
<td>Closing of the WebEx session</td>
<td>5’</td>
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## Annex III – Action Points

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<thead>
<tr>
<th>Nr.</th>
<th>Action</th>
<th>A.P.</th>
<th>Person responsible in</th>
<th>Due date</th>
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<td></td>
<td><strong>NHD</strong></td>
<td><strong>ECHA</strong></td>
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<tr>
<td>1.</td>
<td>Clarification on the source and dissemination of biocides C&amp;L data by ECHA; Clarification on confidentiality status of the data in the assessment report;</td>
<td>1.5</td>
<td>n/a</td>
<td>Jan WEBER HelpNet Secretariat</td>
</tr>
<tr>
<td>2.</td>
<td>Clarification on developing guidance to address the issues with BPR Union applications and similar uses.</td>
<td>1.5</td>
<td>n/a</td>
<td>HelpNet Secretariat</td>
</tr>
<tr>
<td>3.</td>
<td>Feedback from NHDs on the suggested technical improvements of HelpEx, e.g. improving the usability, friendliness, focusing on the keyword approach.</td>
<td>3.3</td>
<td>All</td>
<td>HelpNet Secretariat</td>
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