

17 June 2015

HelpNet BPR Workshop: summary of discussions

Time Wednesday 18 March 2015, 14:00 – 17:00

Place ECHA Conference Centre, Annankatu 18, Helsinki, Finland

1. Opening of the workshop

The moderator of the workshop, Johan Nouwen (ECHA), welcomed the participants with a tour-de-table of the participants.

2. Discussions on replying to helpdesk questions on BPR

2.1. The role of ECHA helpdesk in replying to helpdesk questions

Henna Piha (ECHA) presented the role of ECHA helpdesk in replying to helpdesk questions. In accordance with the BPR (Article 76(1)(d) and Article 76(1)(e)), ECHA's task is to provide support to national helpdesks (NHDs) and advice and assistance to applicants for the approval of an active substance or its inclusion in Annex I to the BPR or for a Union Authorisation. Competent Authorities, on the other hand, need to advise applicants and other interested parties on their responsibilities and obligations under the BPR Regulation (Article 81(2)). Based on this, national biocides helpdesks are the first contact points for industry on many topics whereas ECHA's scope for providing support is more limited.

Currently the ECHA Helpdesk receives many questions on BPR which are not within its remit. Due to resource constraints, the ECHA Helpdesk has to limit the provision of advice and assistance to industry to questions that are within the remit of Article 76(1)(e) or closely linked to ECHA's processes (see Annex 1). The goal is to achieve this by without compromising the service provided to companies.

When customers (both EEA and non-EEA) approach the ECHA Helpdesk with questions outside of its remit, the ECHA Helpdesk will from now on direct these customers to the appropriate national BPR helpdesks. Where customers submit enquiries with multiple questions touching on issues in the remit of the national helpdesks and the ECHA Helpdesk, the ECHA Helpdesk will reply to those questions that fall under ECHA's responsibility but would refer the customers to their national helpdesk for all other questions. If an enquiry cannot be easily split, the ECHA Helpdesk will try to address all questions, clarifying that further information should be obtained from the relevant NHD(s).

Action Point: All national BPR helpdesks to verify the contact list published on ECHA's website (<http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks>) and inform the HelpNet Secretariat on changes needed.

2.2. Dealing with scope questions in HelpEx

HelpEx is the platform for NHDs to discuss questions and agree on harmonised replies for questions within their mandate. National BPR helpdesks started using the platform in autumn 2013 and have since then posted over 60 questions. They have also agreed on 15 FAQs. A

large proportion of BPR HelpEx questions are currently timed-out, indicating the need to clarify the role of ECHA's Helpdesk, the NHDs and the European Commission when dealing with BPR questions.

The participants discussed issues related to the process. NHDs that post questions on HelpEx need to remember to: verify the feedback given to their HelpEx questions; provide a final reply; and close the question or set it to 'unsolved', as appropriate. Many of the timed-out questions touch upon issues, where the European Commission's view would be needed. The European Commission has clarified to ECHA that it will not contribute to the HelpEx discussions directly within the HelpEx platform contrary to the initial expectations. Therefore, HelpNet needs to agree on a new process that will be supported by all involved parties.

One participant had observed that scope questions are brought to the attention of Member States via various channels. As this was to some extent not very transparent, it is difficult to be aware of all of them. The participants also pointed out that there might be a risk that national BPR helpdesks discuss a specific question in HelpEx while the European Commission develops another opinion in parallel. In general, the national BPR helpdesks expressed increasing concern about the lack of involvement of DG SANTE in providing answers to helpdesk questions on biocides. Active participation of DG SANTE in HelpNet events would be desirable as some of the questions are directly addressed to them.

Action Point: All owners of timed-out HelpEx questions to verify the status of their questions and either close them or set them to unsolved. This will allow the HelpNet Secretariat to identify the question that require further follow-up.

Action Point: ECHA to draft a paper with a proposal on how to deal with BPR questions in HelpEx. The draft proposal will be uploaded in CIRCABC for comments.

2.3. Article 95 awareness raising: status and need for support

The participants did not identify activities related to the Article 95 awareness raising that could be done together or that would need further support from ECHA. The national helpdesks had provided the translations for ECHA's Article 95 banners and they were encouraged to use them and link them with ECHA's Article 95 webpage.

ECHA informed that in order to increase transparency ahead of the 1 September 2015 deadline for the compliance with Article 95 of the BPR, ECHA will publish a list of all pending Article 95 applications by the end of March 2015. The list which contains the applications for which ECHA has not yet taken a decision will be updated regularly and its publication will be synchronised with the list of relevant substances and suppliers ("Article 95 list").

3. Hands-on training on R4BP 3.2 and the SPC editor

The participants received hands-on training on R4BP 3.2 processes, new functionalities and the SPC editor. The training focused on key errors carried out by industry when dealing with the IT tools, common misunderstandings with IT tools and focused on the activities of the coming months, i.e., renewal of national authorisations and C&L notifications. R4BP 3, IUCLID 5 and the SPC online editor were used as part of the exercise. The participants valued the opportunity to test by themselves how BPR processes have been technically implemented.

Annex I BPR topics within the remit of the ECHA Helpdesk

Requirements of Article 76(1)(e)

- Active substance approval and Annex I inclusion*
- Union authorisation

Processes under ECHA's responsibility:

- Article 95
- BPC procedures
- Classification, labelling and packaging
- Data requirements
- Data sharing, including the inquiry process
- Dissemination
- ECHA fees
- R4BP3.2 technical questions
- Review Programme Management*
- SPC editor technical questions
- Submission of applications in R4BP3.2*
- Technical equivalence and chemical similarity check

Guidance and support:

- ECHA guidance
- ECHA website

* Where applicable, the relevant NHD/eCA should be contacted by the enquirer

Annex II List of participants

Members of HelpNet

Croatia: Silva KAJIC

Czech Republic: Katerina HRUSKOVA

Finland: Tapio KORKOLAINEN

Italy: Raffaella PERRONE

Latvia: Julija BROVKINA

Lithuania: Dovile PETUKAUSKIENE

Netherlands: Cornelia KOMEN

Norway: Suzanne GORDON

Poland: Renata KAMINSKA

Romania: Mihaela DRAGUSANU

Slovakia: Maria SKULTETYOVA

Spain: Judit MARTIN ARRIBAS

United Kingdom: Amy JOHNSON

Candidate country observers

Serbia: Jelena GRUJIC

Turkey: Pinar OZGUN

ECHA staff

Representing the Units: A1, A2, B2, C1, D1.