HelpNet BPR Workshop: Summary of Discussions

Time Wednesday 2 September, 09:00 – 17:00

Place ECHA Conference Centre, Annankatu 18, Helsinki, Finland

Opening of the workshop

The moderator of the workshop, Henna Piha (ECHA) welcomed the participants followed by an opening speech by Andreas Herdina, Chair of the HelpNet Steering Group.

Session 1: Implementing the Biocidal Products Regulation

1. Reflections on the learnings from the Biocides Stakeholders' Day

Part I: Break-out group discussions

Part II: Discussions with HelpNet and ECHA on

- *Article 95*
- *Union authorisation*
- *Review programme*

Video conference Q&A with the European Commission on BPR implementation, Pierre Choraine (DG SANTE)

As an outcome of the break-out group discussions, the participants presented questions to ECHA and the European Commission for further discussion. In the following, the main discussions topics are summarised.

Review Programme Regulation (EU) No 1062/2014 (no longer supported substances)

In relation to Annex II, Part II of the Review programme (Commission Delegated Regulation (EU) No 1062/2014), companies who are interested to support these substance/product-type combinations have to submit a notification to ECHA. The information requirements for notifications are listed in Annex I to the Review Programme Regulation and include information on the substance identity and intended uses and exposure.

The European Commission confirmed that substances for which no notification has been received by the deadline (30 October 2015), i.e. are no longer supported, will be removed from the list and subsequently should be removed from the market. After the deadline, ECHA will inform the European Commission about the received notifications based on which a preliminary document listing candidates to be excluded will be prepared (for which notifications have not been submitted and for which a non-approval decision will be taken).

National helpdesks and Member States are able to search in R4BP 3 for all notifications which ECHA has received up to date. The search needs to be conducted by searching for

a case type CS-APP (http://echa.europa.eu/support/dossier-submission-tools/r4bp/supporting-documents) which has been used as a workaround.

Review Programme (upcoming deadlines)

Several Member States expressed their concern over there being no single place to follow Review Programme deadlines. It was explained that ECHA is preparing a website where all deadlines will be available in one place. The website is now available at: http://echa.europa.eu/regulations/biocidal-products-regulation/upcoming-deadlines

Confidentiality of the Article 95 list

The participants discussed how the confidentiality of companies is addressed under the BPR, particularly for those listed in the Article 95 list, and what the similarities are with REACH. ECHA clarified that the manufacturer of an active substance is not confidential information.

Article 95 list and its enforcement

Apparently, many companies are concerned about the enforcement of Article 95, especially after its deadline on 1 September. One of the questions asked by companies is whether there is a period of grace for the substances in the Article 95 list. The European Commission clarified that officially there is no period of grace for Article 95. However, Member States may want to show some flexibility with enforcement for at least six months after the deadline, due to the possible low level of awareness of the deadline among companies.

The participants also discussed the fate of applicants who submit their application or Letter of Access (LoA) after the deadline. Will such companies be approved, revoked or placed in a pending list? The European Commission confirmed that companies can submit Article 95 applications even later, in particular for new substances.

Letter of intent to supply

The national helpdesks provided positive feedback on the *Letter of intent to supply* - a document signed by the supplier of an active substance which declares that it supplies the active substance to the recipient. The letter can be specific for a single product or general for all the recipient's relevant products. This differs from a Letter of access (LoA), where the LoA grants a permission to refer or to submit data requirements.

The national helpdesks asked for clarification on how to react in case a downstream user has not gotten a letter from their supplier informing them that the supplier is on the Article 95 list.

The European Commission confirmed that the *Letter of intent to supply* is the first step in checking what the situation is within the supply chain. In principle, there should be a transitional period with enforcement. If a Letter of Supply or a LoA is revoked, then the Member State Competent Authorities need to collaborate with such companies and see their intention and good will before proceeding with sanctions.

R4BP3 training for Member States

The participants requested a practice run for R4BP 3, in particular those who missed the training provided the previous time. The participants also requested access to an R4BP 3 testing environment. ECHA explained new training opportunities are foreseen and further

support options are being assessed.

Classification and Labelling under the BPR

The participants indicated that it is not clear what kind of information should be provided on the label of an active substance, in particular in case of in-situ substances. For example, it was not clear if a precursor must also be indicated on the label.

The European Commission clarified that in principle both precursor and the active substance could be on the label. However, the precursors are not subject to authorisation when they are not placed on the market with the intention to be used for a biocidal purpose. For those which are placed on the market with the intention to be used for a biocidal purpose, the labels of BPR apply (in accordance with Article 69 of the BPR). It is very important to identify properly the active substance. It should be clear to a user and inspector what the product is and what hazards it might have. The label should be in the language of the country where it is placed on the market.

It was acknowledged that the issue can be complex, and the Member States were invited to propose the topic for further discussions at a Competent Authorities meeting. It was also suggested to place the question in HelpEx for further discussion and a common approach.

"Eco/environmental-friendly" labels

CLP and BPR do not allow labels such as eco-, environmental-friendly, etc. However, the Regulations allow labels with a "similar" description. The national helpdesks discussed the meaning of "similar" and asked whether there is guidance for the naming of such products. The European Commission clarified that there is no guidance on this matter. It was commonly agreed that there is a need to discuss this topic further, and the Coordination Group meeting could be the appropriate forum for this purpose allowing Member States to exchange information on how they deal with such labels.

Enforcement of treated articles

The participants asked whether there will be enforcement activities on treated articles, how Member States should collaborate, and whether certain activities should be coordinated by Forum. The European Commission explained that the first meeting with Competent Authorities to discuss enforcement of treated articles is planned for the next year. One of the points of interest is to get information on what is the percentage of companies that are complaint in this area. However, it was still early to conclude something concrete.

Union Authorisation and parallel trade

The national helpdesks wanted to know if it is possible to apply for Union Authorisation and parallel trade. ECHA explained that these two processes are mutually exclusive and cannot be mixed. The same rule (two different processes) also applies for single products and families.

CIRCABC

The participants requested the European Commission to archive or create separate folders with obsolete documents in the CIRCABC site for the BPR Competent Authorities. The general concern was how to make the entire site more user-friendly. It was clarified that there are no near future plans to update the site.

Manual of Decisions

The National Helpdesks noted that the Manual of Decisions is still available at the CIRCABC with the last modification dated to January 2014. However, the document does not contain a disclaimer that it is no longer valid. The participants wanted to know if there is a plan to prepare a consolidated version of still valid decisions. The European Commission clarified that they do not plan to make consolidated version and the disclaimer is pending to be added.

Session 2: Supporting companies

1. Towards harmonised helpdesk replies

Henna Piha (ECHA) introduced the second session with a presentation concerning the role of ECHA and national helpdesks, the handling of HelpEx questions, and the FAQ update process in view of the HelpNet's mission to promote consistent and harmonised advice to companies.

The introduction was followed by a presentation by Hannu Mattila (FI) with observations from the perspective of a national helpdesk. The observations included ambiguity of the types of questions which are for HelpEx, on the role of national helpdesks and the procedures for dealing with different type of biocides related questions. Some proposals from Hannu Mattila included:

- Organising phone conferences to discuss HelpEx questions for which Member States have dissenting views;
- Providing easy access to the most relevant/final documents of the BPR Competent Authority meetings;
- Including important outcomes of Competent Authority meetings in the HelpNet Update;
- Differentiating the HelpNet Update topics as CLP, REACH, or BPR related.

The two presentations served as thought starters for subsequent break-out group discussions dedicated to best practice, as summarised below.

Handling of HelpEx questions

The discussions focused on the management of unsolved questions on HelpEx. Unsolved questions are often identified as scope issues which can be addressed to different bodies: the Coordination Group, the Biocidal Products Committee, the European Commission or the Competent Authority meeting for Biocides. When unsolved questions are in ECHA's remit (or when ECHA contacts directly the European Commission) the regulatory advice team posts the result of the discussion on HelpEx.

When the question is taken to the Competent Authorities, the owner of the question (the one who flagged it as unsolved) needs to follow up the discussion and post a reply on HelpEx. The ultimate goal is to create a valid and useful knowledgebase open to all HelpNet members.

An 'Article 3.3 request' is an important tool which can be used by Member States in order to tackle scope issues (and therefore unsolved questions) directly with the European Commission. Article 3.3 decisions are legally binding decisions under the BPR. During the discussion in the break-out group some weaknesses of this particular provision were highlighted: a heavy administrative burden for Member States, time consuming and demanding in term of resources.

Unsolved questions can be connected to the previous Manual of Decision. All participants considered the document valuable although it is no longer valid. During the discussion the need to replace the Manual of Decision was stressed and the need to publish Article 3.3. decisions as Q&As was highlighted (see also section "Development of FAQs outside ECHA's remit").

FAQ updates

The participants discussed the FAQ update procedure from two main angles: experiences with the FAQ update procedure which had become operational in June 2015, and if the FAQ update process should be enhanced (e.g. by publishing also FAQs which are related to topics outside the scope of ECHA).

Related to the new FAQ update procedure the participants had experienced no difficulties. However, they found that the process could become even smoother by applying certain best practice:

- Proposing FAQs: For a HelpEx question to be considered for the FAQ update procedure, the entry needs to be flagged as 'FAQ' first. Besides from the HelpNet Secretariat which has administrator rights, only the owner of a HelpEx question can flag it as 'FAQ', and this only when closing it in HelpEx. National helpdesks wishing to flag the HelpEx entry as 'FAQ' for which they are not the owner, or which is already closed, need to ask the HelpNet Secretariat to do this on their behalf. However, as best practice national helpdesks could inform the owner of a HelpEx question through the 'feedback' function that they would like to see the entry as FAQ proposal. When closing the HelpEx question, the owner can then flag it immediately as 'FAQ'.
- Commenting on FAQ proposals: The participants were wondering if they should post their agreement on draft FAQs or final draft FAQs on HelpEx even if they have no comments (according to the Step-by-step Guide on the Publication of FAQs on the BPR, CLP and REACH 'no comment' is considered as tacit agreement). They concluded that this would indeed be preferable because it gives assurance to all other HelpNet members that a proposal has sufficient support.
- Launch of FAQ consultation steps: The HelpNet Secretariat had informed HelpNet of the cut-off dates for flagging HelpEx questions as 'FAQ', the subsequent dates for the launch of the first and second consultation rounds and commenting deadlines. In practice, certain draft FAQs and final draft FAQs were ready earlier than anticipated, and the HelpNet Secretariat had launched the respective consultation rounds earlier than initially announced (without changing the commenting deadline). The participants appreciated the approach because they will have in these cases more time to comment.
- Information chain in HelpEx: Given that it is not possible to link entries in HelpEx with each other, or to indicate in the FAQs on the ECHA website the number of the corresponding HelpEx entry, the participants considered it as important to find the ID of a published FAQ in the corresponding FAQ proposal on HelpEx. The HelpNet Secretariat assured them that that this would always be the case. In addition, the HelpEx number of an FAQ proposal would always be indicted in the initial HelpEx question (in the 'Comment' field).

Development of FAQs outside ECHA's remit

During the discussions concerning the scope of BPR FAQs and whether it could be widened, the participants raised the following points:

- BPR FAQs outside ECHA's remit: As an outcome of the first BPR FAQ consultation round, two FAQ proposals (HELPEX 12778 and 12779) were phased out because they were in the scope of the European Commission. In addition, the BPR defines processes which are entirely in the scope of the national helpdesks, meaning ECHA is not in a position to contribute to the relevant HelpEx discussions. The participants of the break-out discussion favoured the idea of producing FAQs related to such topics. However, the question of who would be drafting the relevant FAQ proposals remained to be clarified.
- BPR, Article 3.3 decisions: The participants felt that the publication of Article 3.3 decisions on the ECHA website would be beneficial. Currently, the decisions are stored on CIRCABC and difficult to retrieve. Having such relevant information on the ECHA website would facilitate the work of the national helpdesks and benefit companies.
- Database for FAQs and Q&A on ECHA's website: The participants felt that the FAQ/Q&A database is currently difficult to find, even for them, and that also its functionalities were not sufficiently self-explanatory (e.g. how to filter for FAQs).

Action Points:

The HelpNet Secretariat will clarify whether ECHA could contribute to the development of BPR FAQs outside the scope of the Agency and will bring the concerns raised as to the visibility of the FAQ/Q&A database on ECHA's website to the attention of ECHA's web team.

Annex I List of participants

Austria	Peter Schindler
Belgium	Kristof Claes
Cyprus	Andreas Hadjigeorgiou
Czech Republic	Katerina Hruskova
Denmark	Vivi Johansen
Estonia	Evelin Roop
Finland	Hannu Mattila
France	Catherine Gourlay
Germany	Sylvia Gassel
Greece	Vasileios Vagias
Hungary	Dávid Göblyös
Ireland	Patricia Mc Guire
Latvia	Jolanta Staško
Lithuania	Saulius Majus
Luxemburg	Joé Hermes
Malta	Wayne Giordmaina
Norway	Suzanne Gordon
Poland	Renata Kamińska
Serbia	Jelena Grujić
Slovakia	Maria Skultetyova
Spain	Judit Martin Arribas
Sweden	Leif Bengtsson
The Netherlands	Marcel Hulsman
Turkey	Pinar Ozgun
United Kingdom	Ashley Warman
European Commission, DG SANTE	Pierre Choraine (via video conference)
ECHA staff	Representing units A1, A2, B2, C1, D1

Annex II List of acronyms

BPR	Biocidal Products Regulation (EU) No 528/2012
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
FAQ	Frequently Asked Question; harmonised Q&A pairs agreed with ECHA, national helpdesks and the European Commission
LoA	Letter of access
Q&A	Question and answer
REACH	Regulation (EC) No 1907/2006