New R4BP 3 version: Review Programme Regulation and IUCLID 6

What can I expect in the R4BP 3 version to be released in July 2016?

On 5 July 2016, ECHA will release a new R4BP 3 version (3.7). This version will contain the following main features:

a) submission of declarations of interest to notify an active substance/product-type (PT) combination (DI-SUB).
b) submission of notifications for inclusion in the Review Programme through R4BP 3 (RP-NOT).
c) addition, replacement or withdrawal of a participant from the Review Programme through the register (PA-CHG).
d) IUCLID 6 adaptation: the new version of R4BP 3 will only accept IUCLID 6 files (with the '.i6z' extension).

Currently, you can submit notifications and changes under the Review Programme Regulation ((EU) No 1062/2014) through the ECHA website. You can find additional information on ECHA's existing active substance web page.

What happens to notifications and changes according to the Review Programme Regulation before 5 July 2016?

Only approved declarations of interest to notify active substance/product-type combinations in the Review Programme, notifications for inclusion in the Review Programme and changes and withdrawals of participants will be visible in R4BP 3. If you need to know more about on-going notifications or changes according to the Review Programme Regulation, contact ECHA.

IUCLID 6

Why is there a different release date for IUCLID 6 and R4BP 3.7?

As announced in ECHA's news alert ECHA/NA/16/15, IUCLID 6 will be available from 29 April 2016. R4BP 3 will be adapted on 5 July to only accept IUCLID 6 files. IUCLID 6 is made available earlier to help users prepare for the transition to the new software, by downloading and testing the installation and migration from a IUCLID 5.6 database. Until 5 July, submissions of IUCLID files through R4BP 3 should continue to be made using IUCLID 5.

What are the main IUCLID 6 changes relevant to the Biocidal Products Regulation (BPR)?

The key changes for the BPR in IUCLID 6 will be:

- An updated yet familiar user interface. The main concepts are maintained for the preparation of the technical dossier according to the BPR Annex II and Annex III structure.
- New sections added in the active substance dataset:
    - Section 3.8 – Additional physico-chemical properties of nanomaterials
    - New additions in section 4, i.e. 4.5 *Gases under pressure*, 4.8 *Self-reactive substances*, 4.15 *Organic peroxide*, 4.16 *Corrosive to metals*.

- Section 2.9 – *Composition of the purity of the active substance, substance of concern and other substances*.

Can I re-use the same IUCLID datasets once R4BP 3 accepts only IUCLID 6 dossiers?

You can work with substance and mixture datasets if you have migrated the data from IUCLID 5 to IUCLID 6. A migration tool within IUCLID 6 will be available for you to assist you in this process. At the end of the migration process, you will still have your IUCLID 5 database and a migrated IUCLID 6 database. However, please note that any changes made in one database will not be reflected in the other database and that IUCLID 6 data are no longer compatible with IUCLID 5. Useful instructions on how to migrate data to the new version can be found on the IUCLID 6 FAQ webpage.

Can I use the IUCLID 6 report generator tool to generate the summary of product characteristics (SPCs)?

The initial version of IUCLID 6 will not support the generation of SPCs using the report generator tool. ECHA plans to provide the possibility to generate SPCs from IUCLID 6 data, for single products, during summer 2016.

Submissions

What do I need to consider when I make a submission through R4BP 3 after 5 July 2016?

From 5 July 2016, you will need to:

- **For initial submissions:** create a new dossier using IUCLID 6 when a technical dossier is required.
- **For requested updates from your authorities (ECHA or a Member State):** submit a new dossier using IUCLID 6. You need to migrate substance and mixtures datasets from IUCLID 5 to IUCLID 6 before you create a new dossier.

Important note for submitters of data for REACH, CLP and the Biocidal Products regulations: the submission of data for REACH and CLP will be updated to the IUCLID 6 format on 21 June 2016. BPR submissions have to be made using IUCLID 5 until 5 July 2016 and using IUCLID 6 after 5 July 2016. If you are working under these different regulations, we recommend that you plan your migration to IUCLID 6 taking into account these different timelines.

Submission of notifications for inclusion in the Review Programme: when and how?

Currently, you can submit a notification for inclusion in the Review Programme (RP-NOT) using IUCLID 5 and the CS-APP case type option in R4BP 3. From 5 July 2016, a new case type RP-NOT will be available for you in R4BP 3. You can also include other participants in RP-NOT cases.

Do I need to consider any additional changes?

R4BP 3 allows the transparent management of participants supporting a defined active

substance/product-type combination under the Review Programme. Owners of AS-EVA cases (active substance evaluation under the Biocidal Products Directive (98/8/EC)) will need to complete and possibly correct the list of Review Programme participants to reflect in R4BP 3 changes in accordance with Article 10 of Commission Delegated Regulation (EU) 1062/2014. Further instructions will be provided in the R4BP 3 support section.

Support

Where can I find further information?

R4BP 3 support will be updated with new information and manuals will be revamped to provide additional information on the Review Programme Regulation in R4BP 3. New video tutorials for IUCLID 6 will also be available in the support web page. Useful information on migration to IUCLID 6 will be available on the IUCLID 6 website.