

Release note R4BP 3.8 and SPC 2.0

New case types in R4BP 3.8

The following new case types have been added to R4BP 3:

NA-CCL will allow national authorisation to be cancelled at the request of the authorisation holder.

UA-MAC, UA-MIC, UA-ADC and UA-TRS will support change requests by the applicants on Union authorisations.

UA-CAT and **UA-AAT** will allow the Commission to cancel or amend a Union authorisation.

AS-NPT will allow applicants to request for approval of a new product type in an already approved active substance.

UA-NPF will allow a new member to be added in a Union authorisation product family.

UA-BBS will allow applicants to apply for a Union same (family or single) biocidal product from an already authorised (family or single) product at Union level.

In addition, **SA-NOT** has been modified to allow the notification in another market of a single product belonging to a product family holding a simplified authorisation.

Same biocidal product functionalities in R4BP 3

R4BP 3 now supports all the new obligations of the Regulation (EU) No **414/2013** as amended by Commission Implementing Regulation (EU) **2016/1802**.

It is possible to apply for a single same biocidal product starting from an authorised product family, or one that is waiting for authorisation. It is also possible to apply for a same product authorisation at national level starting from an authorised product, or one that is waiting for authorisation, at Union level.

For more information, please consult:

- the Practical guide chapter on same biocidal product authorisation: <https://echa.europa.eu/practical-guides/bpr-practical-guides>
- the new web page on same biocidal product authorisation: <https://echa.europa.eu/regulations/biocidal-products-regulation/same-biocidal-products-authorisation>; and
- the user manuals relevant for the authorisation you intend to apply for: <https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals>

Updated SPC online editor (2.0) to allow structured family applications

The new IT tool version supports the preparation of product family SPCs with a new structure in three levels: family, meta and product.

From product families, it is also possible to automatically generate the relevant SPCs to be used for same biocidal product applications and notifications to another market of products holding a simplified authorisation.

For more information, please consult the SPC user manual:

https://echa.europa.eu/documents/10162/14938692/bsm_03_using_spc_en.pdf

IUCLID SPC report generator plugin

In the IUCLID 6 website, you can find instructions on how to generate the XML file and then import it into the SPC Editor to generate a single product SPC:

<https://iuclid6.echa.europa.eu/support>

Migration of SPC documents

As a result of the adaptation to the new family structure, ECHA migrated all existing family SPCs in R4BP 3 to the new family structure. The automatic migration applied to all cases/assets containing an SPC in R4BP 3.

The process ensures that no data previously contained in SPCs is lost. However, some adaptations will have to be applied to family SPCs whenever R4BP 3 requires their upload in a specific case type. This may happen:

- 1) for on-going cases where applicants have followed the [workaround solution](#) proposed by ECHA in July 2015 and the new family structure has not been provided yet in a structured format; or
- 2) when information available in the SPC has to be duplicated.

For more information, please consult Annex II to the SPC user manual:

https://echa.europa.eu/documents/10162/14938692/bsm_03_using_spc_en.pdf