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Generation of SPC in IUCLID in 2023

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For application of BPR product authorizations, applicants are obliged to submit a Summary of Product Characteristics (SPC), which can be prepared by an online application called SPC Editor prepared by ECHA and fully compatible with R4BP.

This tool can be used by applicants to prepare SPCs for single products, product families and members of the family. Authorities also use the tool to amend and finalise the SPC while granting an authorisation.

In the future preparation of the SPC files must be done in IUCLID and no more with the SPC Editor.



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Applicants will have to use IUCLID to prepare the SPC in.i6z format, archive the SPC dossiers in the IUCLID cloud. Due to the integration between the IUCLID Cloud and R4BP, SPCs can be exchanged easily with authorities.

The work on the integration, design and development is currently ongoing and the tool is expected to be used from May 2023.

You have the possibility to directly contact ECHA (ECHA Helpdesk technical support (R4BP 3 – Request type “SPC Editor”)) via their [contact page](#). In the field “Question” you need to include “SPC Editor into IUCLID feedback” at the beginning.

Sources

SPC Editor

<https://echa.europa.eu/de/support/dossier-submission-tools/spc-editor>

Recommendation on preparing a Summary of Product Characteristics

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