

4 June 2020

R4BP 3.15 and SPC 2.5 release note

Below you can find the new functionalities that have been introduced in the release R4BP 3.15 and in the new SPC version 2.5.

New case types

- AA-AAT – amendment of Article 95 asset (authority initiated)
- AA-UPD – post approval update of scientific information for Article 95 assets (submitted with dossiers)

Enhancements relevant for both authorities and industry

- A new icon reports on the read/unread status of messages in the panel of R4BP 3 home page
- The "Archive" tag has been revised in the messages panel, making it Legal Entity specific
- The SPC option has been included in NA-RNL application and resubmit task
- The National authorisation transfer link expires when there is a positive/negative decision on the transfer
- The case and asset documents tab in R4BP 3 has been enhanced: it is now possible to search and filter documents
- A new layout of the ad-hoc communication interface has been developed for the TO & CC Recipients lists
- The visibility of delegations/ nominations/ transfers in R4BP 3 has been enhanced
- The "Valid from" filter has been added in the search engine

Enhancements relevant for industry

- The expiration date filed has been introduced for Article 95 assets. This feature is intended to prepare the structure to link the Article 95 R4BP 3 assets with the dissemination website in the future, by establishing a link between the Article 95 asset with the validity of the relevant Active substance or Annex I category 6 assets. It is currently introduced by default as an empty field, which might be populated by the industry applicant or authority via amendment case type (AA-AAT or AA-ADC). If the validity is not populated, the asset will not expire.
- In the PA-CHG case type is now possible to launch multiple join and replace cases
- When applying for SN/SA case types, R4BP 3 provides a SPC Validation message to inform if the selected Active Substances is not part of the Annex I list, and consequently preventing the submission

Enhancements relevant for authorities

- A communication message and an email notification are sent to MSCA when an applicant resubmits in the context of a case
- When a Simplified Authorisation asset is cancelled, a message is sent to the Competent Authorities where there is a notification (SN)
- Authorities are now able to update the validity period for expired assets, by making them active again
- The MSCA Validation task item has been removed in the AS-RNL process
- The cancellation of Simplified Authorisation (SA-CAT) initiation task will be limited to evaluating Competent Authority

SPC enhancements

- The code of the SPC language is now available in the cover page of PDF and Word SPC print out
- The market area name is reported at trade name level, but clearly separated
- Headings at target organisms level are introduced in the PDF and Word SPCs to flag the type of name introduced
- Decimal numbers are now marked with commas in PDF and Word SPC versions
- Standard phrases are introduced in the draft Word SPC for marking an expected prospective asset number, and MetaSPC suffix for product family SPCs
- Only first level headings are displayed in the SPC PDF Table of Contents