

6 July 2022

R4BP 3.21, 3.22 and 3.23 release notes

Below you can find the new functionalities that have been introduced in the latest three releases of R4BP 3: 3.21, 3.22 and 3.23.

Enhancements relevant for both industry and authorities

- A new tab called Events can be used to search and retrieve events from all the cases matching the filters indicated in the search criteria. Export of the results in .csv format is also possible (3.22)
- It is now possible to report in R4BP 3 if a substance is candidate for substitution (3.23)
- A new tab reporting on the history of the transfers performed on a specific asset and on the entities that owned it over time has been made available at asset details level (3.23)
- When a substance is flagged as "candidate for substitution" a corresponding flag indicating the need for comparative assessment is reported in the products where the substance is part of the composition (3.23)
- It is now possible for non-EU entities to trigger AA-TRS cases (3.23).

Enhancements relevant for industry

- In applications for product authorisations under mutual recognition in sequence, the wizard now offers the option to simultaneously submit multiple NA-MRS applications from a reference asset (3.22).
- Also featuring in applications, at the submission wizard, the user is asked to set the contact person via a drop-down list to enhance the follow-up for a given contact in a given legal entity (3.23).

Enhancements relevant for authorities

- In the context of National authorisation applications concluded with a negative decision, authorities will be able to launch a case to revert it, should a favourable appeal launched by the applicant take place (3.22).
- When tasks managed by specific authority users have to be reassigned, the others that can be selected now belong to a list of users with only active accounts (3.22).
- When "change of substance identity" is selected as option during the active substance approval process, a table reporting the cases impacted (both in active substance and product applications) is made available (3.23)

New case types

- **NA-APL** – flow to review negative decisions on applications for authorisation, because of appeals -applicable to NA-APP – (3.22) and applicable to NA-MRP (3.23)
- **UA-CCL** – cancellation of Union authorisation under applicant request

SPC enhancements

- Co-formulants in the product composition of biocidal product families which are reported with 0% concentration at meta-SPC or product level in the XML file will not be reported in the .pdf and Word export (3.21)
- The list of active substances in SPC Editor now shows only those having at least one AS/PT combination with the status Approved (i.e. engaged in a previous approval case that was positively concluded) or Under Review (i.e. engaged in a case still ongoing) (3.22).

