3 December 2020

R4BP 3.18 and SPC 2.7 release note

Below you can find the new functionalities that have been introduced in R4BP 3.18 and in the new SPC version 2.7.

Enhancements relevant for both authorities and industry

- The relation diagram has been introduced to facilitate the identification of reference and concerned Member States in processes to manage major and minor changes of national authorisations (NA-MIC and NA-MAC) and renewals (NA-RNL).
- The Validation task has been introduced in the processes to manage major and minor changes of Simplified Authorisations (SA-MAC and SA-MIC), according to the provisions of the BPR regulation.

Enhancements relevant for authorities

- In the case details dossier tab the user can now find a link that opens directly the IUCLID file associated to the case.

SPC enhancements

- If during product family SPC preparation, the user selects an Active Substance which is pre-flagged as "generated in situ", it will be possible to introduce in the composition of each product of the family a concentration range for that Active Substance. This feature does not prevent to introduce a specific concentration, if needed. Active Substances already selectable in the SPC editor which are generated in situ have been automatically flagged by migration exercise. The flag is not editable in SPC editor, but in order to introduce/amend it, it's required to report the corresponding information in the IUCLID file supporting the application.
- Active substances not approved have been removed from the list of active substances available for selection in the SPC editor.
- The PDF export of the SPC has been improved to make sure that trade names displayed in the corresponding table are always aligned with their respective market area of reference.
- The function for non-active substances has been populated with the value "Non-active substance" in the PDF and Word export, so that the field will not be left empty.
- Page numbers have been added in the Word export of the SPC file (both in single product and product family SPC files).
- A number of fields that used to be reported in free text have been improved introducing the headings: "Method(s)"; "Detailed description of the method"; "Application rate(s)"; "Dilution"; "Number and timing of application".