

23 October 2018

R4BP 3.12 and SPC Editor 2.3 release note

Below you can find the new functionalities in R4BP 3 and SPC Editor.

SPC Editor enhancements

- The SPC Editor now has a new functionality for finding and replacing text. The search applies to all free text fields in a specific file, returning a list of all results. A result points you directly to the section where the result was found.
- The content of the SPC can now be exported into a Word file.
- The 'Function' field for substances of concern and other substances is no longer a mandatory field. In addition, even if indicated, the function will not be printed in the exported pdf and Word file.
- The SPC Editor now supports superscript font formatting in free text fields.
- The printed version of the SPC no longer indicates the market area beside each trade name, to avoid the market area being considered part of the trade name. However, the information on the relevant market area where the trade name is applicable will still be viewable in the SPC XML file.

R4BP 3 – features relevant to industry and authorities

Improved communication/notification

- A new 'Cc' field allows users to copy recipients in a message. The functionality is available for simple messages or messages for which a reply is required. However, only recipients entered in the 'To' field will have the 'Reply' task created for them.
- 'Reply' and 'Reply all' functions have been added to messages. The 'Reply' function sets as the 'To' recipient only the original sender of the message. Through 'Reply all', the system prompts as new recipients all the original addressees in the 'To' and 'Cc' fields.
- All messages can now be exported in pdf format and printed.

Improved user interface

- The list of document types in each drop-down menu is now reported in alphabetical order.
- The timestamp (24-hour format) and the time zone are now reported in the R4BP 3 user interface and in the automated messages.
- The details of every Review Programme-related case type can now be downloaded in pdf format and printed, including the list of participants, when applicable.
- The case type name for AS-REV and AN-REV has been now updated to 'Review of approval of Active substance' and 'Review of approval of Active Substance in Annex I'.

Improved workflows

- Two controls have been introduced in R4BP 3. It will now be possible to apply for simplified authorisation only if the product contains an active substance listed in Annex I. In addition, it will be possible to apply for technical equivalence only starting from an approved active substance.
- The possibility to request IUCLID files during the peer review phase has been introduced. All the processes involving active substances will now contain the option



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'Request additional information' in the drop-down list of the ECHA Opinion task item.

- A bug in the context of the Review Programme implementation has been fixed. With this, AS-NLS (active substance no longer supported) cases for a specific active substance/product-type will no longer be initiated if there is still a Review Programme notification active asset.
- A bug that prevented applying for RP-NOT (Review Programme notifications) starting from active substance/product-type combinations with a still active publication period has also been fixed.

UK's withdrawal from the EU

New features have been developed to support the database adaptations to be
performed following the UK's withdrawal from the EU. The features are currenly hidden
from users, but will be triggered by ECHA by the withdrawal deadline. The features will
reflect in the system the agreements reached by the EU and the UK, as well as those
reached by industry and authorities on the progress of existing and future cases.

R4BP 3 - Features relevant to authorities

Improved user interface

- By clicking on the 'Assign' task icon, authorities will be able to see the names of the potential assignees in alphabetical order.
- Authorities, when requesting further information from the applicant during the
 evaluation of a case, will be able to attach SPCs in XML format in the 'Please choose a
 file to upload' field.

R4BP 3 – New case types

• **AA-CCL**: This case type supports the cancellation, under the request of the applicant, of an asset in R4BP 3 representing the inclusion in the list of active substance suppliers (Article 95).