15 November 2017

R4BP 3.10 release note

Below you can find the new functionalities in R4BP 3.10.

Features relevant to both industry and authorities

Improved search and display

- The new tab “Relation diagram” has been introduced in the case and asset details. This makes available a graphical representation, in a tree structure, of the relations between mutually recognised and back-to-back cases and assets. Designed to improve the traceability of cases, the diagram is a snapshot of companies’ product portfolios and of the related ongoing processes.
- The search filters and options for cases and assets have been improved through the introduction of:
    - multiple selectable values in all the fields where single selectable values used to be available;
    - new filter criteria for assets generated by mutual recognitions or same biocidal products;
    - the possibility to search by company name.
- The export functionality of R4BP 3 has been enhanced to support the generation of a worksheet reporting the content of all visible fields in the case and asset details (i.e. product name, active substance name, trade name, etc.).

Improved communication

- The messaging system has been enhanced, providing the possibility to search through sent and received messages by extended filtering options (i.e. product name, trade name, company name, case type, etc.). The possibility to archive messages has also been added. Messages tagged as "Archived" are not searched by default, unless explicitly requested by the user.

Improved workflows

- The process of redefinition of an active substance (within the Review Programme – **AS-EVA**) is now supported. This functionality allows industry users to update, at the request of the authority, the substance name of one or more substances into a new one on the basis of the outcome of redefinition.
- The process “change of substance identity” has been introduced to enable the applicant to correct, at the request of the authority, a mistake in the dossier on the substance name.
- The evaluation of the notifications of products holding simplified authorisation to other

markets is now automatically completed if the Member State does not conclude the evaluation within 30 days.

SPC enhancements

- In both biocidal product family SPC and single product SPC, it is now possible to select multiple product types for each use.
- The error generated when special characters were copied and pasted into the editor has been fixed.

Features relevant only to industry

Improved communication

- R4BP 3 now allows case owners to initiate a dialogue with the competent authorities by sending a direct message. The functionality, however, does not allow the possibility to require a reply (i.e. to set a deadline for a response) from the authority.

Improved workflows

- It is now possible to apply for mutual recognition of the same biocidal product in market areas where the original product has already been authorised.
- A new and more user-friendly SPC upload functionality has been implemented in R4BP 3 to support the submission of grouped applications.
- Applicants are now able to notify in different markets one or more products holding simplified authorisation (either single products and/or members of product families) through one software wizard. To align the IT options with the authorities' interpretation of the Biocidal Products Regulation, notification of a whole product family is no longer supported.

Features relevant only to authorities

Improved communications

- It is now possible to select directly the deadline date for the reply in an *ad hoc* communication, instead of counting the number of days to that deadline.

Improved workflows

- The system now supports the synchronisation of the tasks performed by reference and concerned competent authorities when evaluating applications for **national authorisation with Mutual Recognitions (NA-APP, NA-MRP)**. With this feature, new steps have been introduced to new submissions or existing submissions for which the evaluation has not yet started. These steps support the process of agreement on

the draft SPC and the referral to the Coordination Group, synchronising deadlines and actions among reference and concerned competent authorities. Whenever an application for national authorisation does not have any concerned case in mutual recognition, the workflow will not be changed.

- When the evaluation of an **application for simplified authorisation (SA-APP)** is ongoing and the provision of further documentation is performed by the applicant upon request, the evaluation timer was mistakenly not reset (to 90 days). This issue has now been fixed.

New case types

- **AS-UPD and AN-UPD**: Two new case types to support requests of further information made by the evaluating competent authorities during the BPC opinion stage of the active substance approval (AS-APP or AN-APP) or active substance evaluation (AS-EVA) processes that have to be provided after the Commission decision. The new case types allow applicants to update the set of information of an active substance asset by submitting new scientific data (e.g. IUCLID files or Doc III documents).