R4BP 3.9 release note

Below you can find the new functionalities in R4BP 3.9.

New case types

Initiated by industry

- **AN-CHG (1-5) and AN-CHG (6)** - to amend active substances entries in Annex I (Industry initiated) falling in category 1 to 5 and in category 6.
- **SN-ADC and SN-CCL** are cases that allow amending or cancelling already existing simplified authorisation notifications.
- **PA-CHG applied to RP asset** – to support the addition or removal of participants during the validity period of review programme assets (approved notifications of inclusion of active substances in the review programme).
- **UE-NOT –** to notify to the Commission an unexpected or adverse effect of a product that came up after a Union authorisation was granted.

Initiated by authorities

- **AS-REV –** to support the process of revision of an approved active substance triggered by the Commission.
- **DE-APP -** essential use derogation, to allow competent authorities to authorise for a limited period the use of certain biocidal products containing active substances not approved.

Features relevant for industry

Enhanced grouping

- Extended grouping submissions are now supported for administrative changes (ADC). Applicants are able to select assets of different type (NA, SA, UA) for which they would like to launch a grouped ADC. So far, this feature was only available for assets linked by mutual recognition. The outcome will be a set of single cases launched in parallel, which Member State competent authorities will evaluate one by one.

Improved synchronisation

- The problem related to already open cases blocking the wizard of submission of grouped RNL, ADC, MIC, MAC assets has been fixed.

Improved processing of cases

- Industry can now submit a same biocidal product application in parallel (NA-BBP) with a mutual recognition in sequence (NA-MRS) case as context starting point.
- Applicants can now withdraw a case.
- Case owners and asset owners can now transfer a case.
- The nomination of the case owner is now available also for cases related to the review programme.
- The non-approval date in AS-EVA and AS-NAS is now recorded in the system to allow the submission of DE-APP.

Features relevant for authorities

Enhanced grouping

- Competent authorities working in a grouped ADC evaluation will be able to conclude a concerned case evaluation without waiting for the reference case to be finalised.
- It is now possible to include a new case in an already existing NA-ADC, NA-RNL, NA-MIC, NA-MAC grouped submissions.

Improved synchronisation

- This is for renewal of applications linked via a mutual recognition: now, the nature of the dossier evaluation (full or light), initially defined by the reference Member State, will be the default evaluation type for the concerned Member State (rMS).

Improved communication

- This option for ad-hoc communication for competent authorities allows the user to quickly select all concerned Member States for a mutual recognition case.
- Automatic notifications are now sent to concerned Member States when the reference Member State has closed a case (i.e. the final SPC was uploaded) in mutual recognition cases.

Improved processing of cases

- The file upload for competent authorities in the VAL/MEV/EVL task items is not mandatory anymore.
- Upon asset creation for mutual recognition, same biocidal product or notification, the concerned Member States can independently define the "valid from" date for their assets.
- The issue of wrong due date caused by multiple and/or long "stop the clock" actions has been fixed.
- Competent authorities can now extend deadlines for resubmission without opening a new resubmission request.

Features relevant for both industry and authorities

Improved display and search

- The search by product name and active substance is now possible without having to define the case type first. In addition, the user can now run a search on multiple case types selected at the same time.
- For reference cases, a new "grouped cases" section under the "Related cases" tab is available. Here, an improved list of linked mutual recognition cases is available. Please note that this new functionality applies only to newly created cases.
- In the applicant's task list, a new column to display the evaluating Member State is available.
- Assets that will become valid only at a future point in time are labelled as "Inactive" and are searchable in the Asset search engine.
- In the search results interface, the "R" icon now indicates the case number of any reference case for mutual recognitions. Please note that this new functionality applies only to the newly created cases for the time being. We are looking into a solution to apply the new feature to all cases.