

History, development and future of R4BP 3 and SPC editor

Biocides Stakeholders' day IT
training

27 September 2017

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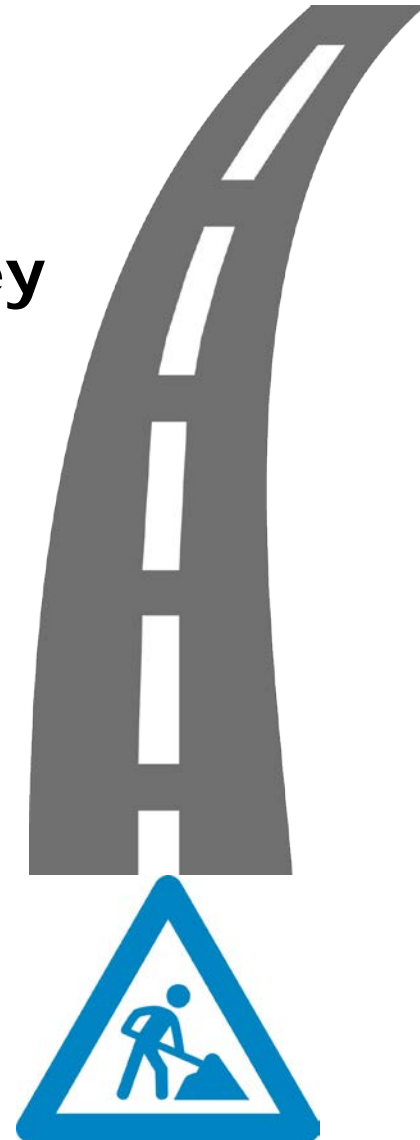
The journey of IT tools

1. The first part of the journey
2. Our current state of play
3. Our destination



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IT tools highlights 2013-2015

21 Regulatory processes
One way communications
Basic search features

5 Regulatory processes

24 Regulatory processes
User interface: links, grouping, renewals

Enhanced Workflows

R4BP 3

2013

2014

2015

SPC Editor

First mandatory SPC format

IT tools highlights 2016

5 Regulatory
processes:
Support to the
Review
Programme

10 Regulatory
processes: Union
Authorisation
Workflow
improvements

R4BP 3

2016

SPC Editor

Updated
SPC:
Product
family



Regulatory processes

- Requirements in the BPR have been implemented as IT processes in R4BP 3 as priority
- Currently, almost all of them are available
 - ✓ National authorisations and mutual recognitions
 - ✓ Union and simplified authorisations
 - ✓ Active substance approvals
 - ✓ Inclusion in Article 95 list and in the Review programme
- ✓ Considering applications, amendments and cancellations (for authorities) there are about 100 processes

The journey of IT tools

1. The first part of the journey
- 2. Our current state of play**
3. Our destination



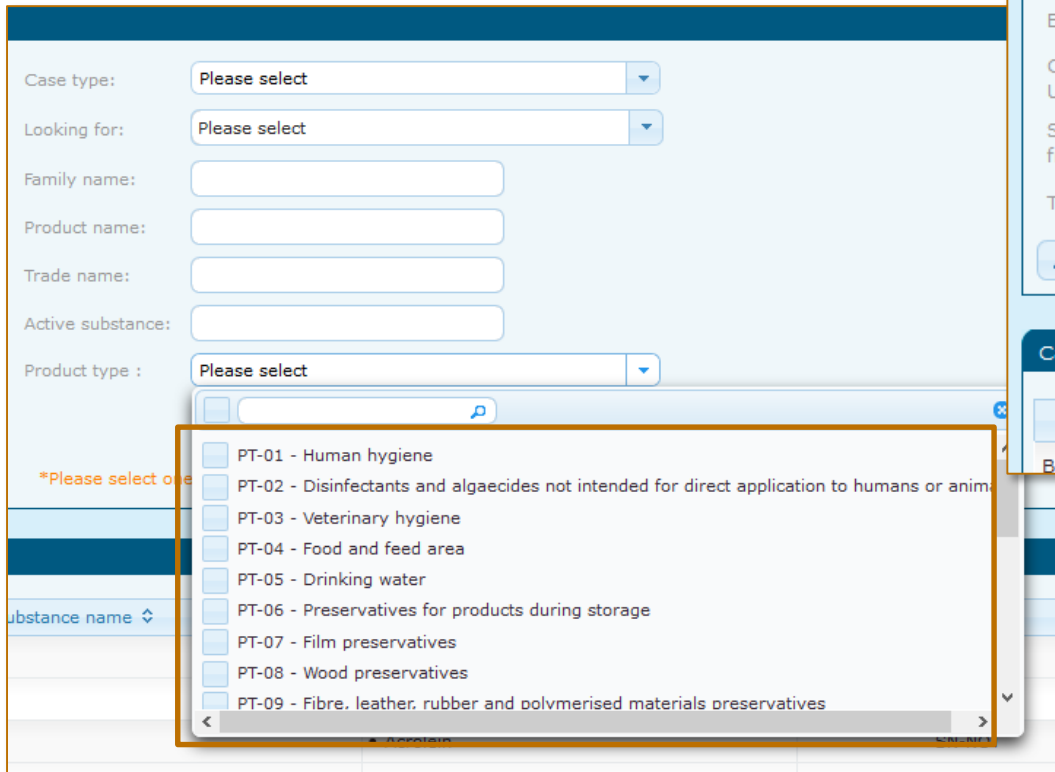


New features in 2017

- User interface improvements
 - ✓ More powerful search options
 - ✓ Improved display of data relations
- Communications enhancements
- Process flow improvements: more flexibility and transparency
- Few remaining regulatory processes

User interface: enhanced search and export

For cases and assets

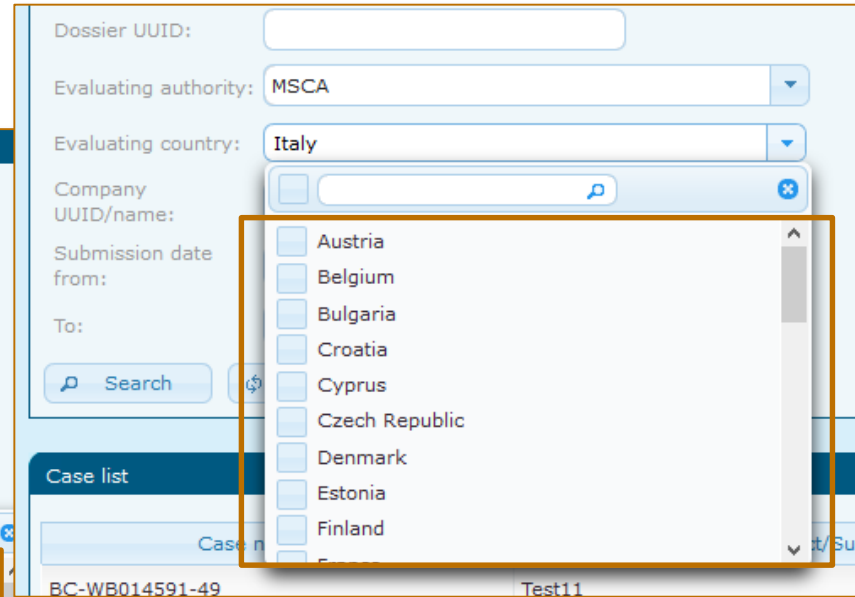


The screenshot shows a search form with the following fields:

- Case type: Please select
- Looking for: Please select
- Family name: [text input]
- Product name: [text input]
- Trade name: [text input]
- Active substance: [text input]
- Product type: Please select

A search bar is located below the product type field. A dropdown menu is open, showing a list of product types (PT-01 to PT-09) with checkboxes:

- PT-01 - Human hygiene
- PT-02 - Disinfectants and algaecides not intended for direct application to humans or animals
- PT-03 - Veterinary hygiene
- PT-04 - Food and feed area
- PT-05 - Drinking water
- PT-06 - Preservatives for products during storage
- PT-07 - Film preservatives
- PT-08 - Wood preservatives
- PT-09 - Fibre, leather, rubber and polymerised materials preservatives



The screenshot shows a search form with the following fields:

- Dossier UUID: [text input]
- Evaluating authority: MSCA
- Evaluating country: Italy
- Company UUID/name: [text input with search icon]
- Submission date from: [text input]
- To: [text input]

A search button is located below the submission date fields. A dropdown menu is open, showing a list of countries with checkboxes:

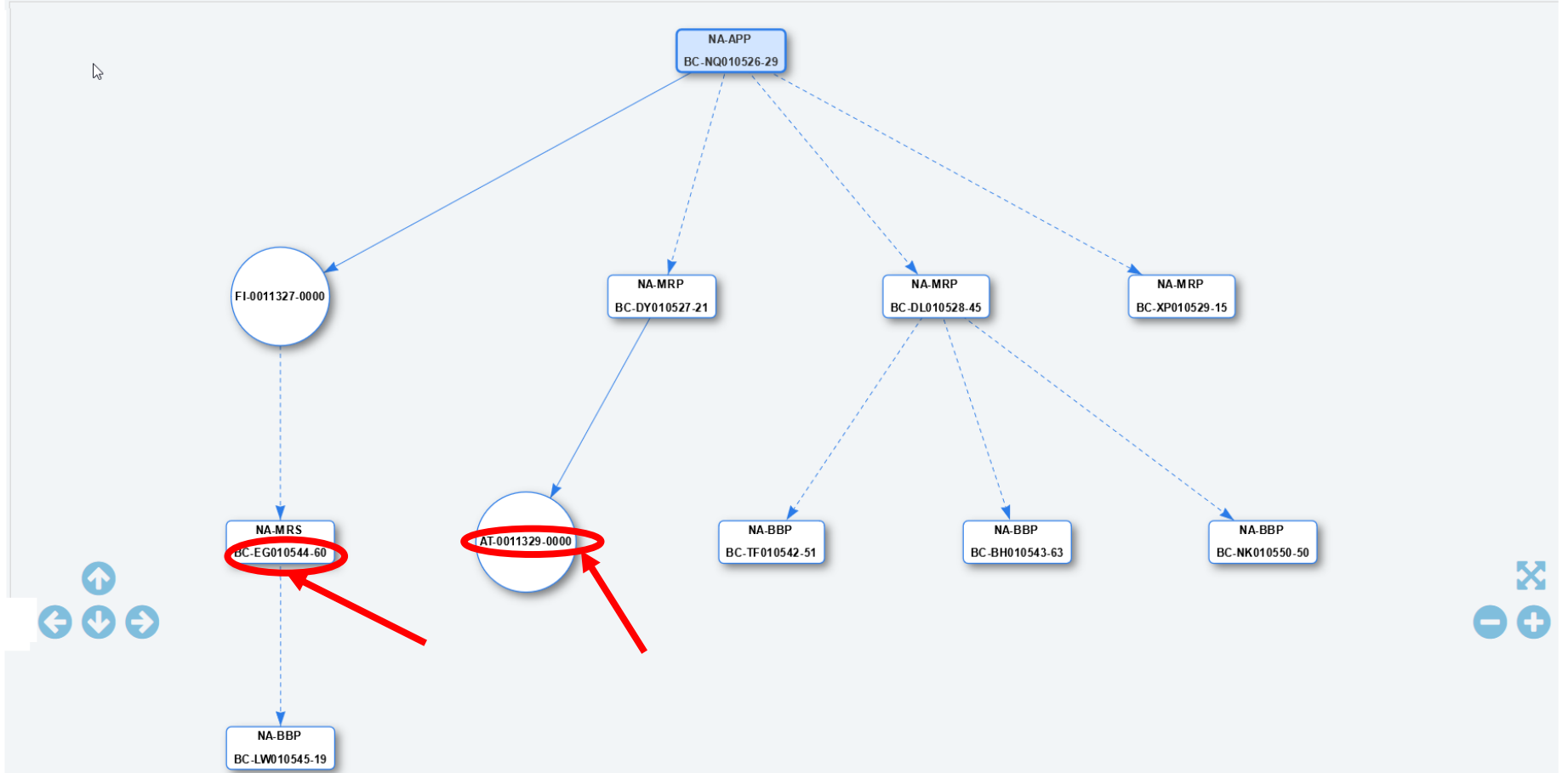
- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland

Below the search form, a "Case list" section is visible, showing a table with columns for Case ID and Substance Name. The first row is: BC-WB014591-49 | Test11

User interface: relation diagram

SPC documents | Dossiers | Company details | Events history | Documents | Financial management | Related cases | **Relation diagram**

- The diagram represents the relations between the current case or asset and other cases and assets.
- Squares represent cases while circles represent assets. Inside squares and circles you may find the case/asset numbers. Above the numbers you may find the case type for cases or the originating case type for assets.
- The current case/asset square/circle is highlighted by default in the diagram. Clicking on any other square or circle will open in a new tab the corresponding case or asset details.
- The arrows in the diagram are solid when the target of the relation is an asset, while they are dotted when the target of the relation is a case.
- If a circle with an asset number does not contain any case type inside it means that the asset is migrated without any associated originating case type.
- If a circle's border is dotted it means that this asset is a family member and it is shown in the diagram because it is the context asset of a case (in the case details diagram) or the causing asset (in the asset details diagram).
- If the label of a circle (asset) is not bold that means that the current user does not have access to the asset details page of that asset (due to the asset being transferred).



Search and archive communications

Welcome, Italy_DNA_1_M_IT

Search for messages

Sent/Received: Sender:

Status:

Archived:

Case number: Message topic:

Case type:

Active substance: Message subject:

Product - Family name: Message number:

Trade name: Date Received From:

Product type: To:

Message list

	Sender	Topic: Subject	Case number
<input type="checkbox"/>	<input type="checkbox"/> MSCA-Germany	Evaluation: The Evaluation of the reference case for the process NA-APP with case number BC-BA009502-76 in the Market area Germany has been finalised	BC-BA009502-76

Case owners can initiate a communication with evaluating CAs

You are [companyAmanager](#) on behalf of [Company Aa \(GR\)](#) ▼

Application for national authorisation (NA-APP): BC-LU014477-14

Case status: In Progress
Evaluating authority: MSCA-Bulgaria
Submission date: 12/09/2017
Completed on: -

Product information
Family name: NA-app scenario 3
Product type(s): PT02
Active substance(s): • Acrolein

[Create new case](#) [Actions](#)

[SPC documents](#) [DE](#) [New communication](#) [Company details](#) [Events history](#) [Documents](#) [Financial management](#) [Related cases](#) [Relation diagram](#)

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- If a circle's border is dotted it means that this asset is a family member and it is shown in the diagram because it is the context asset of a case (in the case details diagram) or the cause of a case.
- If the label of a circle (asset) is not bold that means that the current user does not have access to the asset details page of that asset (due to the asset being transferred).

Process flow: case withdrawal

Application for national authorisation (NA-APP): BC-BA009502-76

Case status: In Progress

Evaluating authority: MSCA-Germany

Submission date: 03/05/2017

Completed on: -

Product information

Product name: Autan Protect Spray

Trade name(s): Autan Protect Spray

Product type(s): 19

Active substance(s): • N,N-diethyl-meta-toluamide

Create new case **Actions**

Download as PDF
Withdraw case

SPC documents Del Company details Events history Documents Financial management Related cases

	DE-Germany
	de (Master)
Autan Protect Spray	download to PDF download in XML

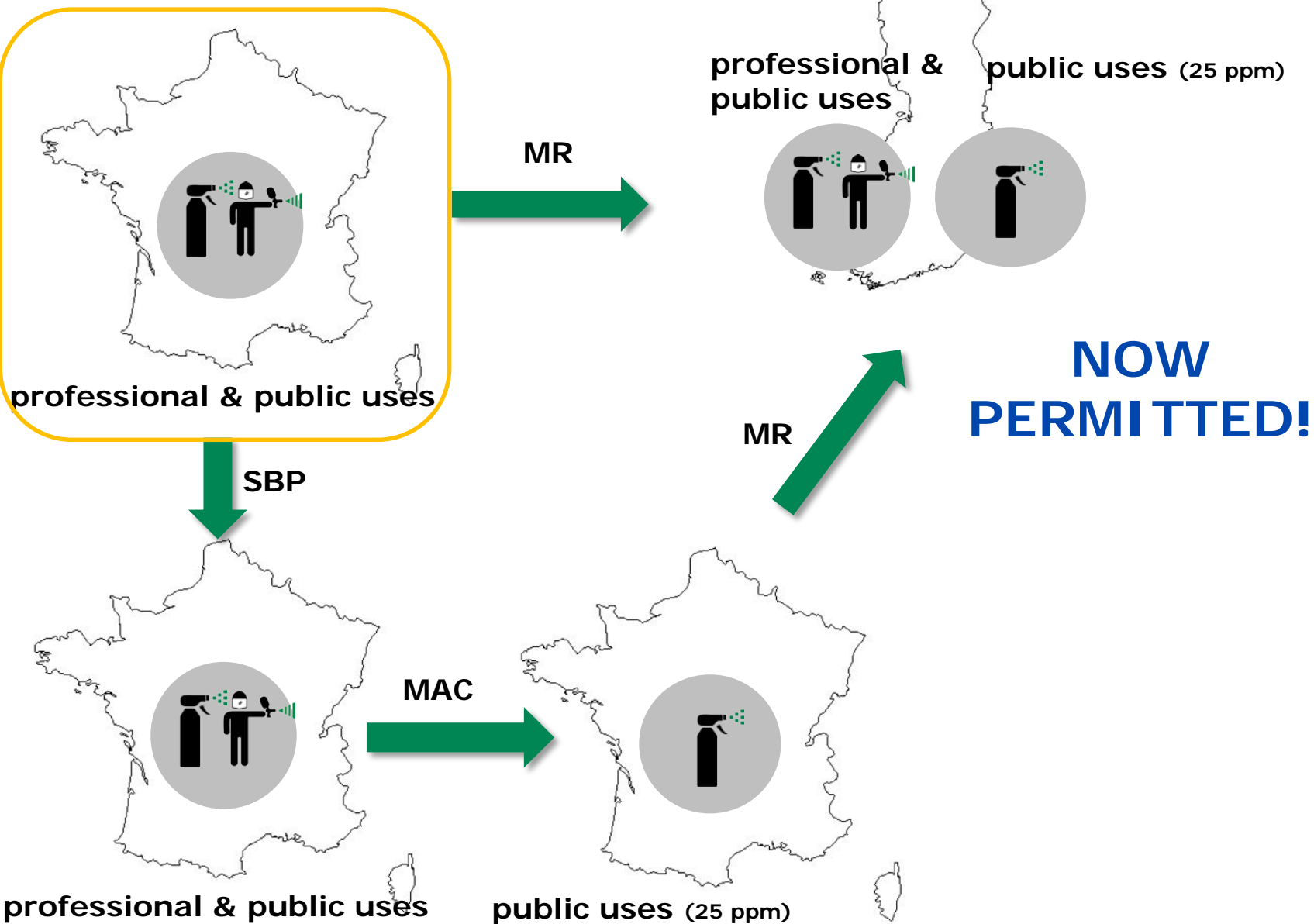
Process flow: case transfer

The second Legal Entity has to accept



The screenshot displays the ECHA application interface for a national authorisation (NA-APP) case. The user is identified as 'bio_user' on behalf of 'Biocides Company (FR)'. The application ID is 'BC-JV009505-20'. The case status is 'In Progress', evaluated by 'MSCA-Finland', and submitted on '03/05/2017'. Product information includes 'Product Family of hands disinfectants', 'Product type(s): 2', and 'Active substance(s): Lactic acid'. A navigation bar contains tabs for 'Actions', 'Dossiers', 'Company details', 'Events history', 'Documents', 'Financial management', and 'Related cases'. The 'Actions' tab is highlighted with an orange circle, and its dropdown menu is open, showing the option 'Accept case owner transfer'. Below the navigation bar, there are buttons for '+ Product Family of hands disinfectants', 'download to PDF', and 'download in XML'. The interface also shows 'FI-Finland' and 'en (Master)' as active elements.

Mutual recognition of SBP



Grouping and synchronisation

- ✓ Synchronisation of the evaluation between reference and concerned Member States in mutual recognitions: transparent process to increase efficiency
- ✓ Enabled grouped submissions of administrative changes not in mutual recognition (NA, SA, UA)

Select assets to include in the submission

Search for assets

 Market area:

* Use the filters below and click 'Search'. See the results in the Assets list.

 Family asset number:

 Family name:

 Assets expiring from:

 Product name:

 To:

 Trade name:

 Company UUID/name:


Search



Clear

Confirm selection

Assets list

* Click on the checkboxes below to select asset(s) and press on the Confirm Selection button

<input type="checkbox"/>	Asset number	Product/Substance name	Active substances	Asset type	Expiration date	Start renewal by	Asset status
<input type="checkbox"/>	EU-0010300-0001	Product 1	• alphachloralose	SA	27/08/2025	24/02/2024	Active
<input type="checkbox"/>	EU-0010300-0002	Product 2	• alphachloralose	SA	27/08/2025	24/02/2024	Active

 Showing 1-2 of 2 results (1 of 1) Go to:

 Show:

Selected assets

* For each asset in Selected assets an individual Administrative change application will be submitted.

<input type="checkbox"/>	Asset number	Product/Substance name	Active substances	Asset type	Expiration date	Start renewal by	Asset status
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No assets selected

 Showing 0-0 of 0 results (1 of 1) Go to:

 Show:



New and improved processes

- Amendment and cancellations of notifications for simplified authorisations
- Review of Active Substance Approval (AS-REV) (3.10)
- Essential Use Derogation (DE-APP)
- Redefinition of active substance
- Streamlined notifications of Simplified Authorisations

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Features planned for 2018

- New case type to support article 95 list amendments
- Workflow enhancements :
 - ✓ Amendments or cancellations of markets where Union Authorisations are applicable
 - ✓ Union Authorisation in EEA countries
- User interface improvements:
 - ✓ Remember filter in search functionality,
 - ✓ Allow amendments of actions done by mistake

Features planned for 2018



- Communication: further flexibility in the messaging system
- Improvements to the SPC editor “compare” feature
- Find and replace text in the SPC editor
- Performance improvements
- Compare biocidal products
- Preparations for Brexit