

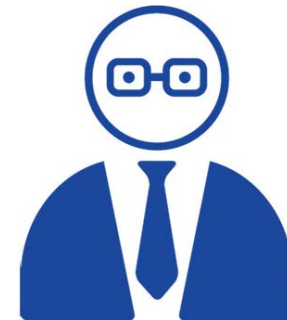
# Introduction to R4BP 3 and Summary of Product Characteristics (SPC) editor

Biocides Stakeholders' day IT  
training

27 September 2017

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R4BP 3 and SPC editor Product Manager  
European Chemicals Agency





## Let's imagine that...

- You are a Regulatory Manager of a SME in Finland
- Your company developed a portfolio (family) of disinfectant products sharing:
  - ✓ Same active substances with similar composition
  - ✓ Similar levels of risk and efficacy
  - ✓ Similar uses
- Your plan is to:
  - Market them in (example) Finland and in Germany
  - Capture customers in Germany sensible to nicer branding
  - Eventually sell the product to another company

## The Biocides Regulation comes in...

To fulfil your plans you need to:

- Get a National Authorisation (NA ) for your product family in Finland
- Get a NA for the same product family, under mutual recognition, in Germany
- Get a NA for only one product of your family as same biocidal product
- Transfer the last NA to another company





## How to do that?

BPR requires you to submit applications and seek authorisations via IT tools:

- ✓ Scientific information on hazards and risks in **IUCLID 6**
- ✓ Administrative information in **SPC** file (one per each application)
- ✓ Submission of the application, communications and recording of the evaluations by Competent Authorities in **R4BP 3**

## Today we will...

- Introduce the basics of R4BP 3 and SPC editor
- Show you how to use them to get your required authorisation by:
  - ✓ Guiding you in a role-play where you will prepare the SPCs and perform the applications in R4BP 3
  - ✓ Demonstrating how Competent Authorities are recording their evaluations
- Summarise the next improvements of R4BP 3

# SPC editor basics



# What is an SPC?

- Standard, electronic and non-confidential component of an authorisation
- It contains public information on
  - ✓ Administrative information
  - ✓ Concentration ranges,
  - ✓ Product and Formulation types
  - ✓ Use information
  - ✓ Risk management measures
  - ✓ Hazard and precautionary statements

Summary of product characteristics for a biocidal product family

Family name: Product family of disinfectants

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

R4BP 3 asset reference number: EU-001568-000

Authorisation number:

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Part 1 - First information level

1. Administrative information

1.1. Family name

Product family of disinfectants

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name	Company
Address	Amsterdam, 1033 BE Amsterdam, The Netherlands

R4BP 3 asset reference number: EU-001568-000

Authorisation number

Date of the authorisation: 2008-01-01

Entry date of the authorisation: 2008-01-01

1.4. Manufacturer(s) of the biocidal product

Name of the manufacturer	Manufacturer 1
Address of the manufacturer	Amsterdam, 1033 BE Amsterdam, The Netherlands
Location of manufacturing site	Amsterdam, 1033 BE Amsterdam, The Netherlands

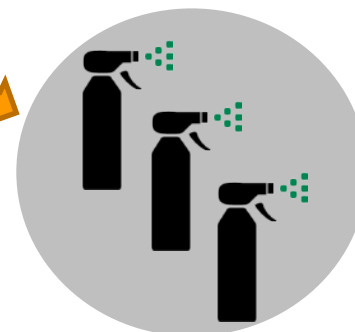
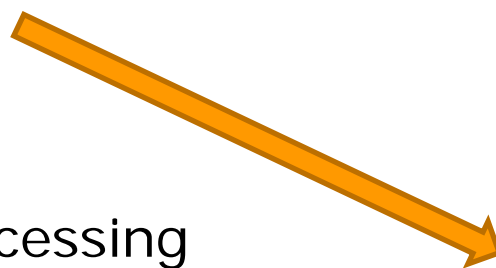
001568-000 SUMMARY OF PRODUCT CHARACTERISTICS 1

## How to prepare it?

- To be filled in electronic format
- The information requirements are different for:
  - ✓ Single products
  - ✓ Product families
- Used for:
  - ✓ R4BP 3 data processing
  - ✓ Dissemination
  - ✓ Comparison

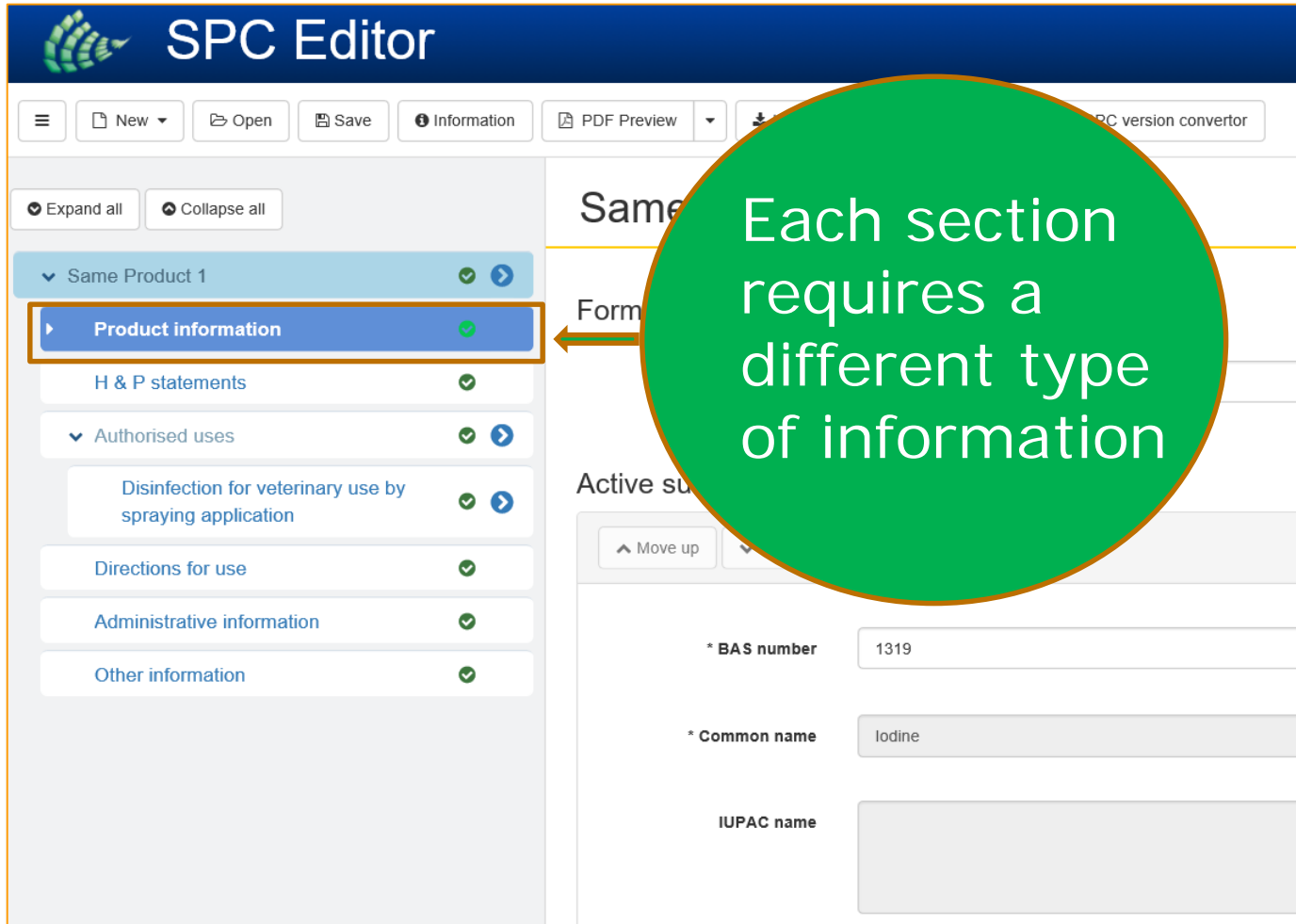


SPC editor





# SPC user interface for single product



SPC Editor

Expand all Collapse all

Same Product 1

Product information

H & P statements

Authorised uses

Disinfection for veterinary use by spraying application

Directions for use

Administrative information

Other information

Same Product 1

Form

Active substances

Move up

\* BAS number 1319

\* Common name Iodine

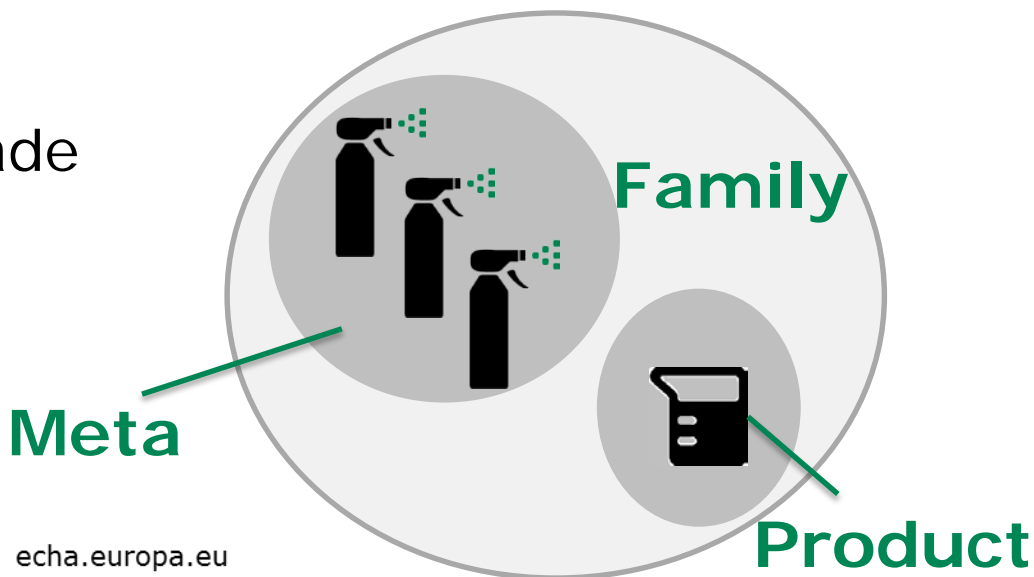
IUPAC name

Each section requires a different type of information

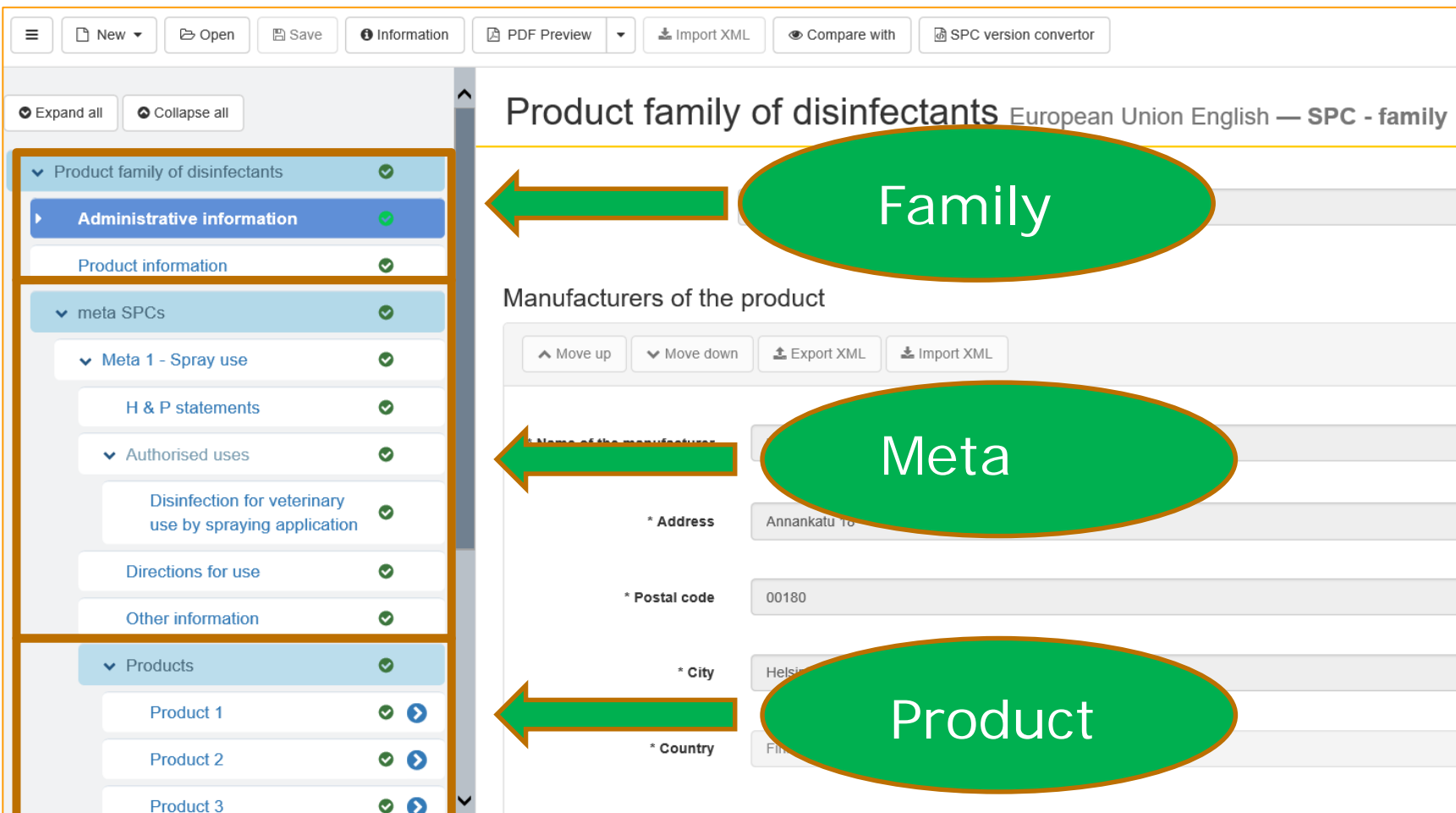
# Product Family SPC

Common information on three levels with new SPC editor

1. **Family** – concentration ranges, product types
2. **Meta** - formulation type, authorised uses, risk management measures, hazard and precautionary statements
3. **Product** - specific concentration and trade name



# SPC user interface levels for a Product family



The screenshot displays the ECHA SPC user interface for a product family. The interface is organized into several sections:

- Product family of disinfectants** (European Union English — SPC - family)
- Administrative information** (checked)
- Product information** (checked)
- meta SPCs** (checked)
  - Meta 1 - Spray use** (checked)
    - H & P statements (checked)
    - Authorised uses** (checked)
      - Disinfection for veterinary use by spraying application (checked)
    - Directions for use (checked)
    - Other information (checked)
- Products** (checked)
  - Product 1 (checked)
  - Product 2 (checked)
  - Product 3 (checked)

Three green ovals with arrows point to the following levels in the hierarchy:

- Family**: Points to the "Product family of disinfectants" section.
- Meta**: Points to the "Meta 1 - Spray use" section.
- Product**: Points to the "Product 1" entry under the "Products" section.

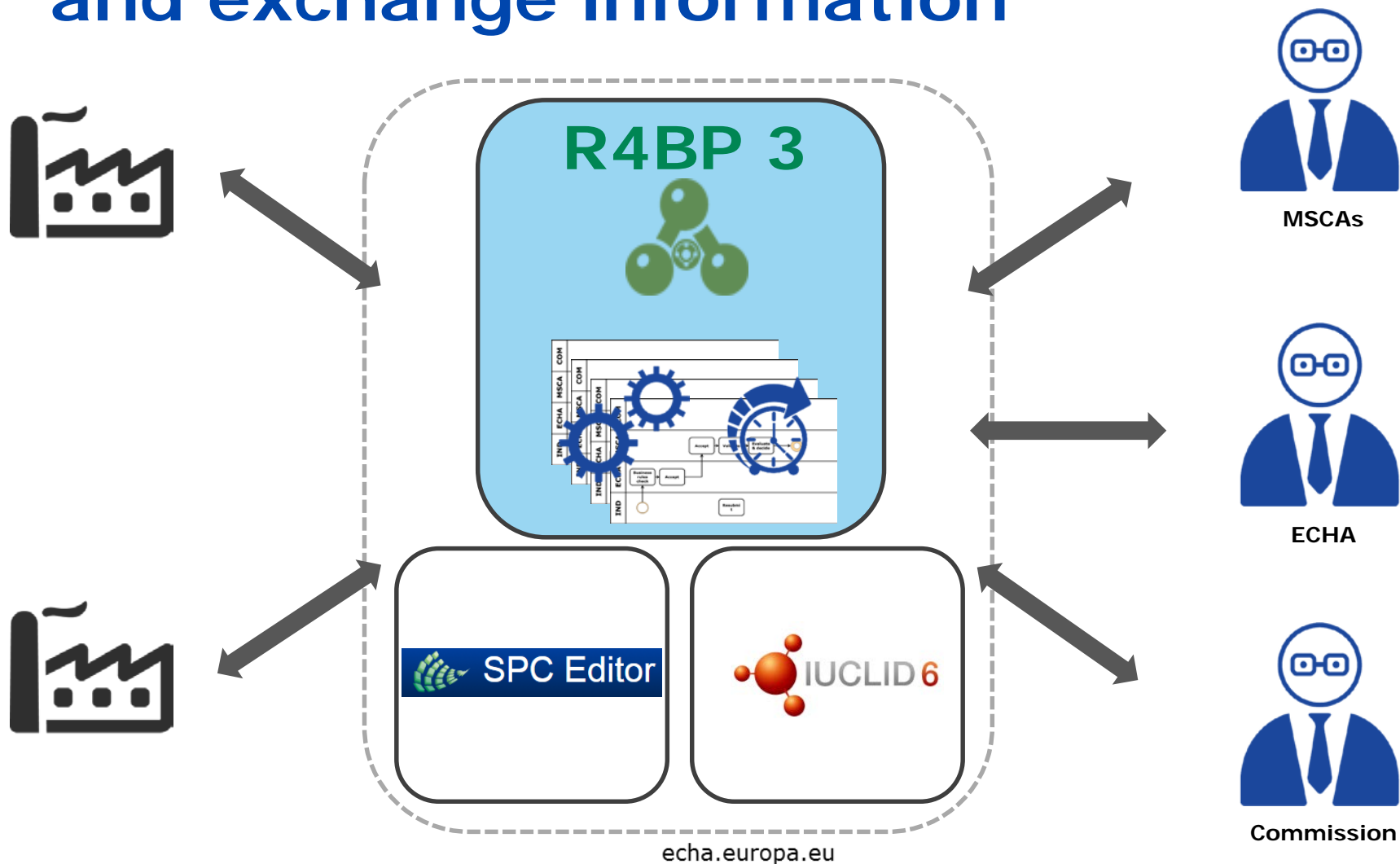
## Today your task is to create...

- One SPC for your market area
- One SPC for the market where you re seeking mutual recognition (change market area)
- One SPC for the application of on single same biocidal product (from the family)

**R4BP 3 basics**



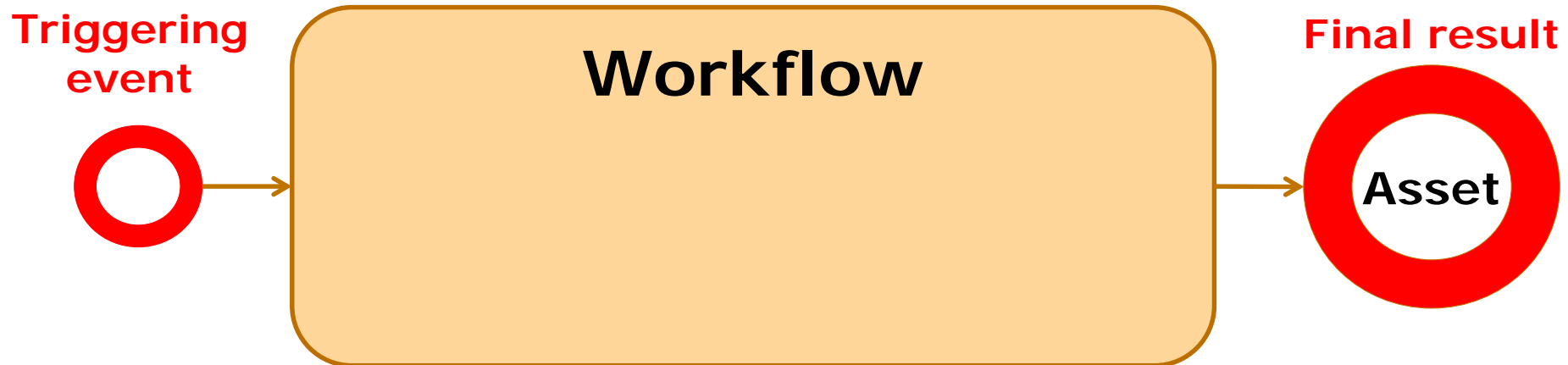
# Central hub to comply with legislation and exchange information



## BPR processes


- Requirements in the BPR have been implemented as IT processes in R4BP 3
- Currently almost all of them are available
- For example:
  - ✓ 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

# BPR processes as IT workflows





# R4BP 3 User Interface (IND)



[TASKS](#)
[MESSAGES](#)
[CASES](#)
[ASSETS](#)
[NEW APPLICATION](#)

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

### Tasks due to expire

Task name	Product/Substance name	Active substances	Due date	Case type
<a href="#">Resubmit information</a>	NA-APP scenario 0906	• Basic Copper carbonate	30/07/2017	NA-MRS <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	aldo_pt3	• aldo_pt3	29/07/2017	AS-EVA <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	-	-	03/06/2016	AS-APP <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	• Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	03/06/2016	AS-RNL <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	tyrosine_sub	-	03/06/2016	AS-EVA <span style="background-color: red; color: white; padding: 2px;">LATE</span>

[See all tasks here](#)

### My messages


From	Topic: Subject	Product/Substance name	Received
Agency		test1	20/09/2017
MSCA-Bulgaria		test1	20/09/2017
MSCA-Bulgaria		test1	20/09/2017
MSCA-Bulgaria		test1	20/09/2017
Agency		test1	20/09/2017
Agency		test1	20/09/2017
Agency		test1	20/09/2017
MSCA-Belgium		test1	20/09/2017
MSCA-Belgium		test1	20/09/2017
MSCA-Belgium		test1	20/09/2017

[See all messages here](#)

**GOOD TO KNOW:**

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# R4BP 3 User Interface (AUTH)


X

TASKS
MESSAGES
CASES
ASSETS

Welcome, echaadmin

### My tasks

Task name	Product/Substance name	Active substances	Due date	Case type
Evaluate & Decide	Leg_Single_v.1.1.1	• p-[(diiodomethyl)sulphony]toluene	03/05/2015	UP-APP <b>LATE</b>
ECHA accept	Warfarin	• Warfarin	12/12/2014	AS-ACC <b>LATE</b>
ECHA accept	Warfarin	• Warfarin	11/12/2014	TE-APP <b>LATE</b>
ECHA accept	Warfarin	• Warfarin	10/12/2014	TE-APP <b>LATE</b>
Evaluate & Decide	Romanas Single	• Methylene dithiocyanate	03/02/2015	UP-AAT <b>LATE</b>
BRC confirmation	Warfarin	• Warfarin	27/01/2016	AS-APP <b>LATE</b>
Initiate communication	-	-	-	TE-APP
Substance information	Test-AS-01	-	12/06/2016	AS-EVA <b>LATE</b>
BRC confirmation	Single Product 002	• Abamectin • Bifenthrin	15/09/2016	UA-APP <b>LATE</b>
Validate	test	• difluzenuron	24/12/2016	UA-BBP <b>LATE</b>

[See all my tasks here](#)

### Messages

From	Topic: Subject	Product/Substance name
MSCA-Belgium	<a href="#">Comments:Reply deadline expired [NMP-C-1023990-08-00/F]</a>	rbp6311_new
MSCA-Finland	<a href="#">Comments:Reply deadline expired [NAD-C-1023994-40-00/F]</a>	Finpinokio
MSCA-Estonia	<a href="#">Authorisation:Reply deadline expired [NMP-C-1019488-96-00/F]</a>	Scenario4_BG
MSCA-Belgium	<a href="#">Confidentiality requests:Reply deadline expired [NAP-C-1023532-46-00/F]</a>	NA-app scenario 3
MSCA-Belgium	<a href="#">Comments:Reply deadline expired [NMP-C-1023584-10-00/F]</a>	rbp6311_new
elenk	<a href="#">Evaluation:Reply deadline expired [NMP-C-1023717-19-00/F]</a>	Scenario1_CY
Agency	<a href="#">Comments:Reply deadline expired [NAP-C-1022480-41-00/F]</a>	rbp6311_new
Agency	<a href="#">Comments:Testing 6425</a>	rbp6311_new
Company Aa	<a href="#">Comments:Reply deadline expired [UMI-C-1022214-29-00/F]</a>	NA-app scenario 3
Agency	<a href="#">Adhoc Invoicing:Reply deadline expired [NMP-C-1022241-26-00/F]</a>	rbp6311_new

[See all messages here](#)

### My group tasks

Task name	Product/Substance name	Active substances	Task status	Case type
Initiate communication	kk04052015 single	• p-[(diiodomethyl)sulphony]toluene	CLAIMED	NA-MRS
ECHA accept	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6)	• Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)	UNCLAIMED	AS-ACC <b>LATE</b>
BRC confirmation	Marmelade	-	UNCLAIMED	NA-ADC <b>LATE</b>
Initiate communication	-	-	CLAIMED	CC-APP
Initiate communication	-	-	CLAIMED	CC-APP
Initiate communication	-	-	CLAIMED	CC-APP

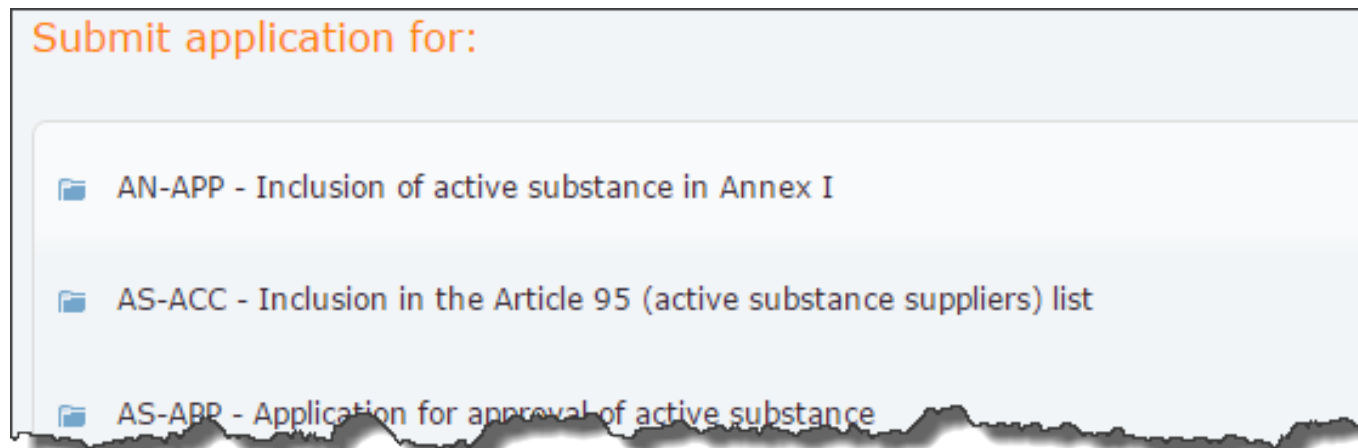
**GOOD TO KNOW:**

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# Triggering event: new Application



- Initial submissions
- Grouped applications (under development)
- Subsequent processes (mutual recognition in sequence)



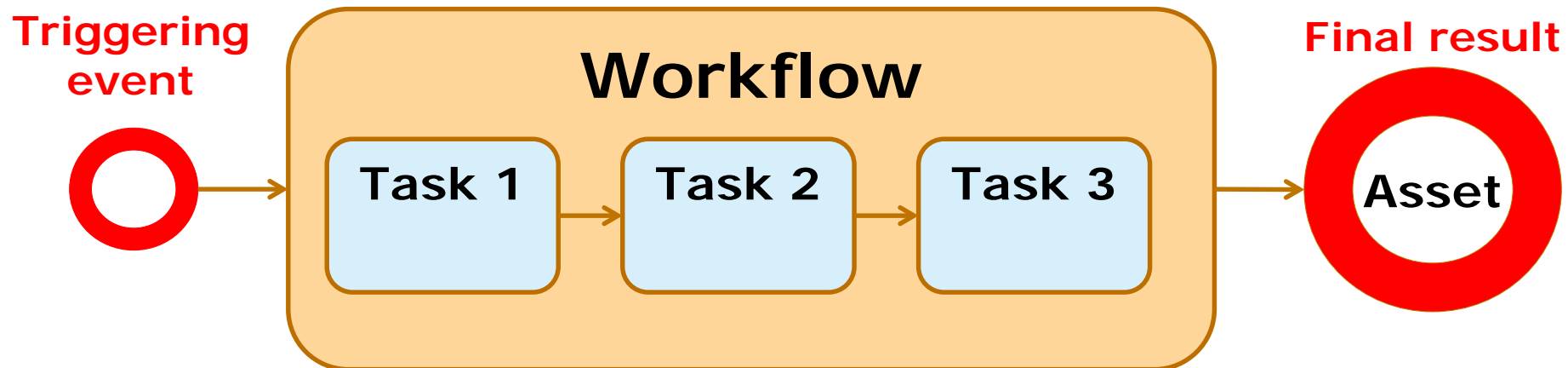
# Assets



- Positive outcome on an application
- Unique asset number

Assets list			
Asset number ▼	Product/Substance name ⇅	Active substances	Asset type ⇅
<a href="#">DE-0003841-0000</a> <b>D</b>	asdf	• Methylene dithiocyanate	NA
<a href="#">DE-0000505-0000</a>	Warfarin	• Warfarin	ET

# Process steps as workflow tasks



## Tasks – You are required to act



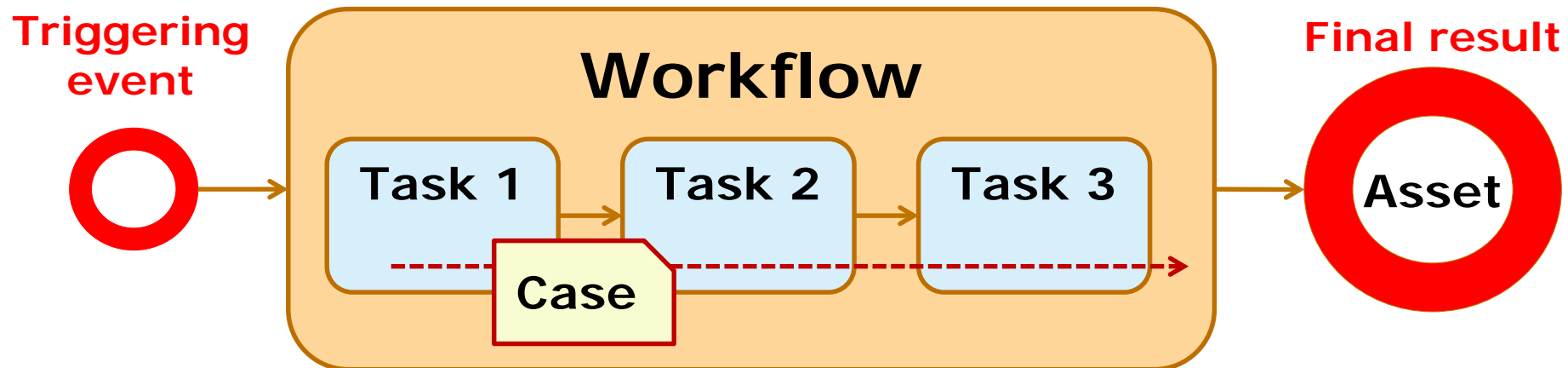
- E.g. Resubmission & Reply (*Process, for Authorities*)
- Due date!
- Email alerts to applicant
- Search / filter / export



The screenshot shows the ECHA Tasks list interface. At the top, there are three buttons: Search, Clear, and Export (.xls). Below these is a table with the following structure:

Task name	Case number
<a href="#">Reply to communication</a> 	<a href="#">BC-TK012895-22</a>

# Sequence of tasks = Case



# Cases – Your submissions



- All ongoing processes
- Detailed permanent event history
- Email alerts to applicant

Date ↕	Step	
06/12/2014 14:59:18	MSCA Acceptance	MSCA acceptance started, due by 05/01/2015
06/12/2014 14:59:15	ECHA Acceptance	Submission accepted by ECHA [ <a href="#">NMP-C-1079424-06-00/F</a> ]
06/12/2014 14:47:15	Submission	ECHA acceptance started, due by 10/01/2015
06/12/2014 14:47:05	Format Checks	Submission format verified [ <a href="#">NMP-C-1079421-09-00/F</a> ]
06/12/2014 14:32:14	Format Checks	BRC confirmation started, due by 08/12/2014
06/12/2014 14:32:06	Submission	Submission format verified for the reference Case
02/12/2014 19:25:37	Submission	Waiting for submission format verification of the reference Case
02/12/2014 19:25:15	Submission	Initial submission [ <a href="#">BC-WY012898-85/1</a> ]




# Messages – Your Communication



- Inbox, Sent, Search
- Attachments
- Permanent records
- Email alerts to applicant

Message list	
From	Topic: Subject
Agency	<a href="#">Submission:Submission accepted by ECHA [NMP-C-1079424-06-00/F]</a>
Agency	<a href="#">Format Checks:Submission format verified [NMP-C-1079420-10-00/F]</a>
Agency	<a href="#">Format Checks:Submission format verified [NMP-C-1079422-08-00/F]</a>

# R4BP 3 User Interface (IND)



[TASKS](#)
[MESSAGES](#)
[CASES](#)
[ASSETS](#)
[NEW APPLICATION](#)

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

### Tasks due to expire

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<a href="#">Resubmit information</a>	NA-APP scenario 0906	• Basic Copper carbonate	30/07/2017	NA-MRS <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	aldo_pt3	• aldo_pt3	29/07/2017	AS-EVA <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	-	-	03/06/2016	AS-APP <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	• Potassium (E,E)-hexa-2,4-dienoate (Potassium Sorbate)	03/06/2016	AS-RNL <span style="background-color: red; color: white; padding: 2px;">LATE</span>
<a href="#">Resubmit information</a>	tyrosine_sub	-	03/06/2016	AS-EVA <span style="background-color: red; color: white; padding: 2px;">LATE</span>

[See all tasks here](#)

### My messages


From	Topic: Subject	Product/Substance name	Received
Agency		test1	20/09/2017
MSCA-Bulgaria		test1	20/09/2017
MSCA-Bulgaria		test1	20/09/2017
MSCA-Bulgaria		test1	20/09/2017
Agency		test1	20/09/2017
Agency		test1	20/09/2017
Agency		test1	20/09/2017
MSCA-Belgium		test1	20/09/2017
MSCA-Belgium		test1	20/09/2017
MSCA-Belgium		test1	20/09/2017

[See all messages here](#)

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X

TASKS
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Welcome, echaadmin

### My tasks

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ECHA accept	Warfarin	• Warfarin	12/12/2014	AS-ACC <b>LATE</b>
ECHA accept	Warfarin	• Warfarin	11/12/2014	TE-APP <b>LATE</b>
ECHA accept	Warfarin	• Warfarin	10/12/2014	TE-APP <b>LATE</b>
Evaluate & Decide	Romanas Single	• Methylene dithiocyanate	03/02/2015	UP-AAT <b>LATE</b>
BRC confirmation	Warfarin	• Warfarin	27/01/2016	AS-APP <b>LATE</b>
Initiate communication	-	-	-	TE-APP
Substance information	Test-AS-01	-	12/06/2016	AS-EVA <b>LATE</b>
BRC confirmation	Single Product 002	• Abamectin • Bifenthrin	15/09/2016	UA-APP <b>LATE</b>
Validate	test	• difluzenuron	24/12/2016	UA-BBP <b>LATE</b>

[See all my tasks here](#)

### Messages

From	Topic: Subject	Product/Substance name
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MSCA-Finland	Comments:Reply deadline expired [NAD-C-1023994-40-00/F]	Finpinokio
MSCA-Estonia	Authorisation:Reply deadline expired [NMP-C-1019488-96-00/F]	Scenario4_BG
MSCA-Belgium	Confidentiality requests:Reply deadline expired [NAP-C-1023532-46-00/F]	NA-app scenario 3
MSCA-Belgium	Comments:Reply deadline expired [NMP-C-1023584-10-00/F]	rbp6311_new
elenk	Evaluation:Reply deadline expired [NMP-C-1023717-19-00/F]	Scenario1_CY
Agency	Comments:Reply deadline expired [NAP-C-1022480-41-00/F]	rbp6311_new
Agency	Comments:Testing 6425	rbp6311_new
Company Aa	Comments:Reply deadline expired [UMI-C-1022214-29-00/F]	NA-app scenario 3
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BRC confirmation	Marmelade	-	UNCLAIMED	NA-ADC <b>LATE</b>
Initiate communication	-	-	CLAIMED	CC-APP
Initiate communication	-	-	CLAIMED	CC-APP
Initiate communication	-	-	CLAIMED	CC-APP

**GOOD TO KNOW:**

- Asset** - In the R4BP 3 context, an asset is a regulatory decision on an application (with a unique asset number) related to either an active substance (e.g. a decision on technical equivalence or the Article 95 list) or a biocidal product (e.g. a national authorisation or a Union authorisation).
- Case** - A case relates to an application and is created after the successful submission of an application (with a unique case number) in R4BP 3 by the Industry users. It includes all the steps in the application process which lead to the creation of, or update of, an asset (the regulatory decision). The purpose of a case is to manage and view the progress of the submission by both the Industry and Authority users.
- Event** - An event is a step whereby information is submitted that is needed in the handling / processing of an application. Examples include the submission of an application, the submission of additional information on the request of the authorities, fee payment, and the communication of a decision.
- Task** - A working item that is created and assigned to specific user groups (Industry or Authority users). A task is created in order to perform and complete certain actions (e.g. request for additional information) that are required from the user. These requests are completed through task items within a defined time period. The task is identified by the task name and is related to a particular case number.

# Role play



## Let's get the authorisations!

- You will have to work together in teams, playing three roles: Industry, Authority and ECHA
- You need to get three authorisations, so you can swap in every process, if you feel like
- First create your SPCs, then submit the applications
- Credentials in the room document
- If needed, test data here: <http://bit.ly/biocidesIT>
- Our observers will help you!

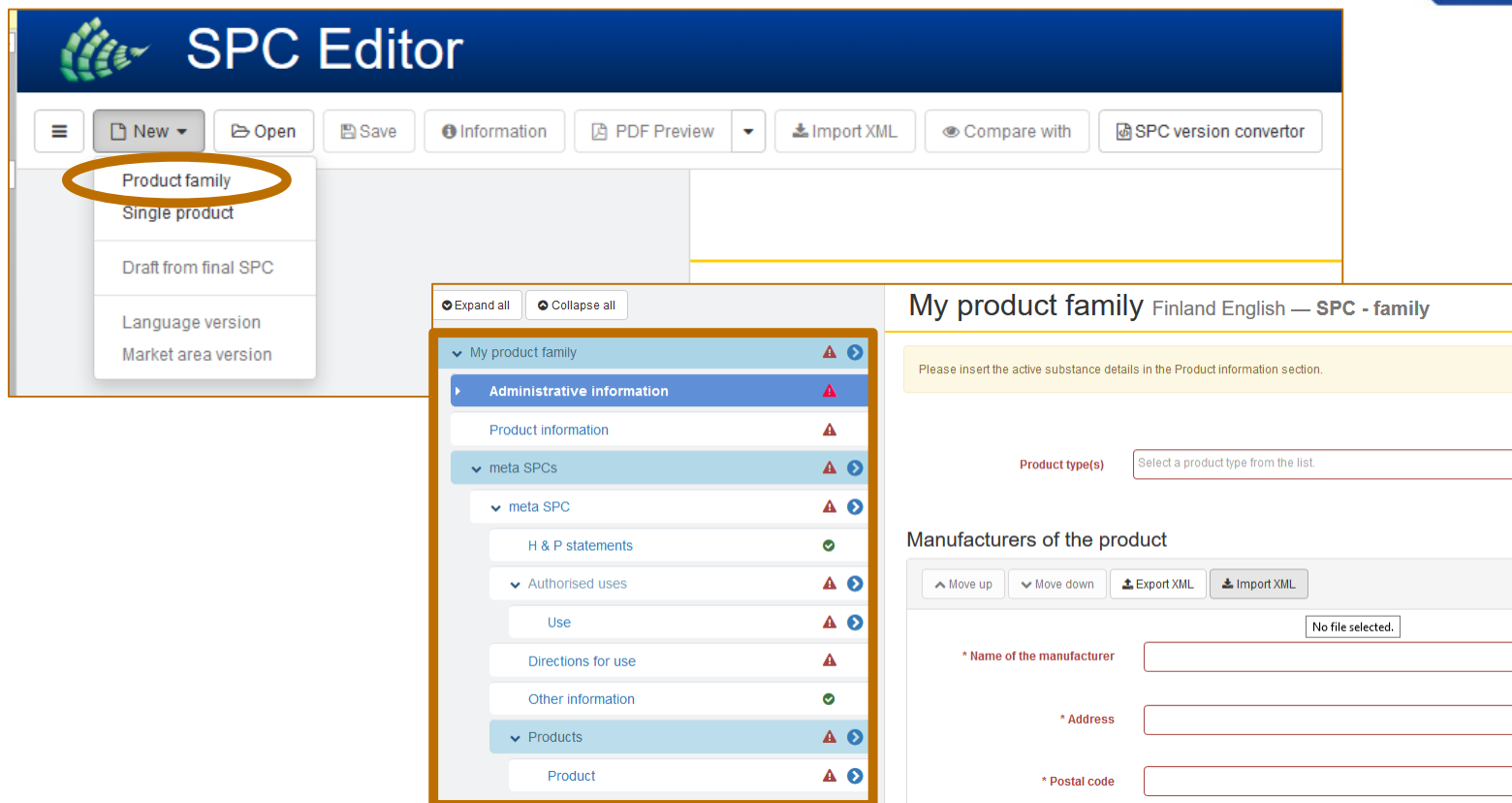
<b>R4BP 3 and SPC editor hands-on session</b>	
	<b>27 September 2017</b>
10:45 – 11:10	Introduction to R4BP 3 and SPC editor
11:10 – 11:50	Exercise 1 (SPC)
11:50 – 12:15	Exercise 2 (NA-APP, NA-MRP)
12:15 – 12:45	Sandwich break
12:45 – 13:25	Exercise 2 (NA-APP, NA-MRP)
13:25 – 13:45	Exercise 3 (NA-BBS)
13:45 – 14:00	New features of R4BP 3 and SPC editor
17:00	<b>END</b>

# Exercise 1 – Create SPCs (40')





# Create a product family SPC



The screenshot displays the SPC Editor interface. At the top, the title bar reads "SPC Editor". Below it is a menu bar with options: "New", "Open", "Save", "Information", "PDF Preview", "Import XML", "Compare with", and "SPC version convertor". The "New" menu is open, showing options: "Product family" (circled in orange), "Single product", "Draft from final SPC", "Language version", and "Market area version".

The main editor area is titled "My product family Finland English — SPC - family". It contains a tree view on the left and a form on the right. The tree view is expanded to show the following structure:

- My product family
  - Administrative information
  - Product information
  - meta SPCs
    - meta SPC
      - H & P statements
      - Authorised uses
        - Use
        - Directions for use
        - Other information
      - Products
        - Product

The form on the right includes a yellow warning box: "Please insert the active substance details in the Product information section." Below this is a "Product type(s)" field with a dropdown menu. The "Manufacturers of the product" section has buttons for "Move up", "Move down", "Export XML", and "Import XML". A "No file selected." button is visible. There are three required input fields: "\* Name of the manufacturer", "\* Address", and "\* Postal code".

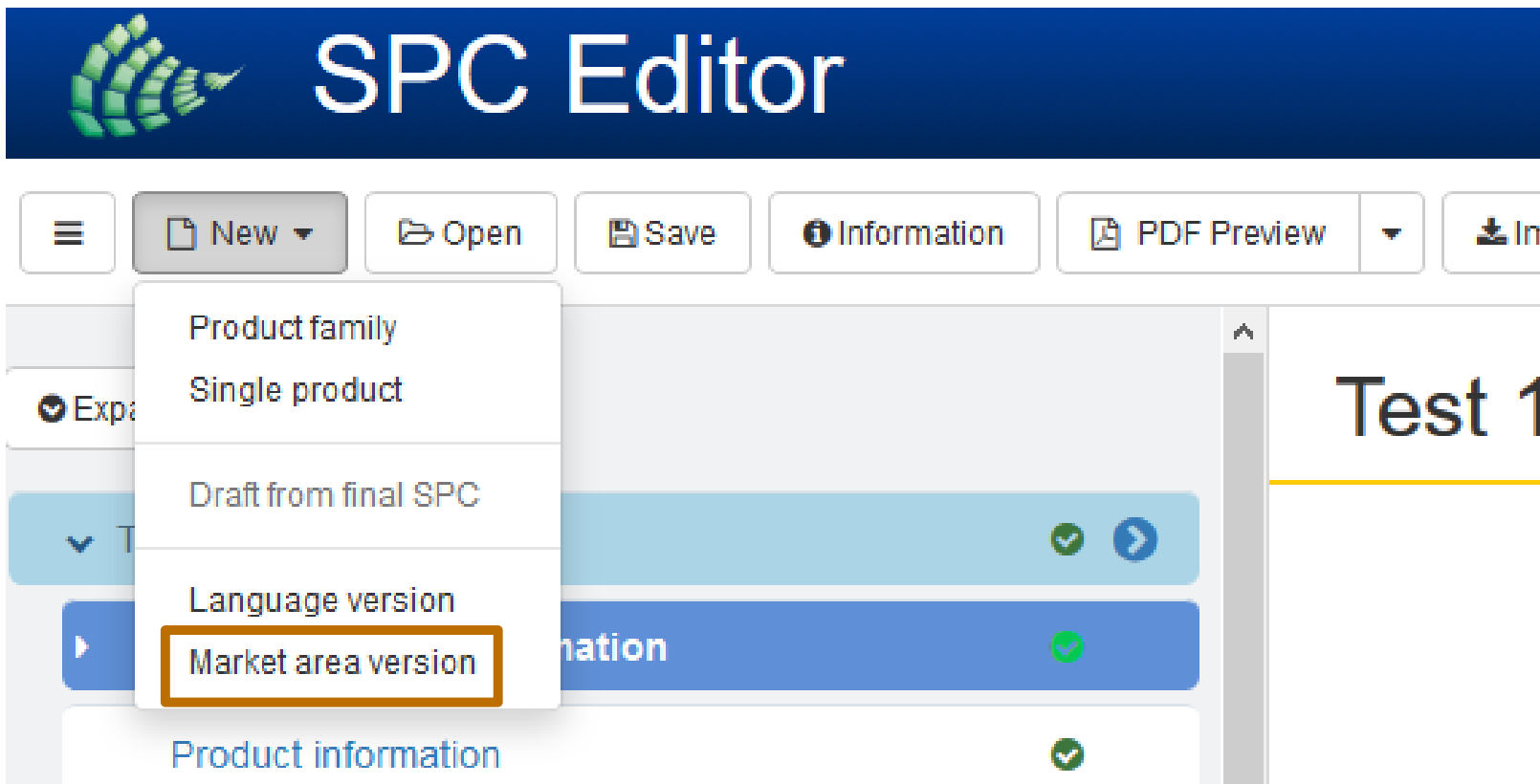


## SPC information for your Product family

You will have to fill in the following information in the SPC

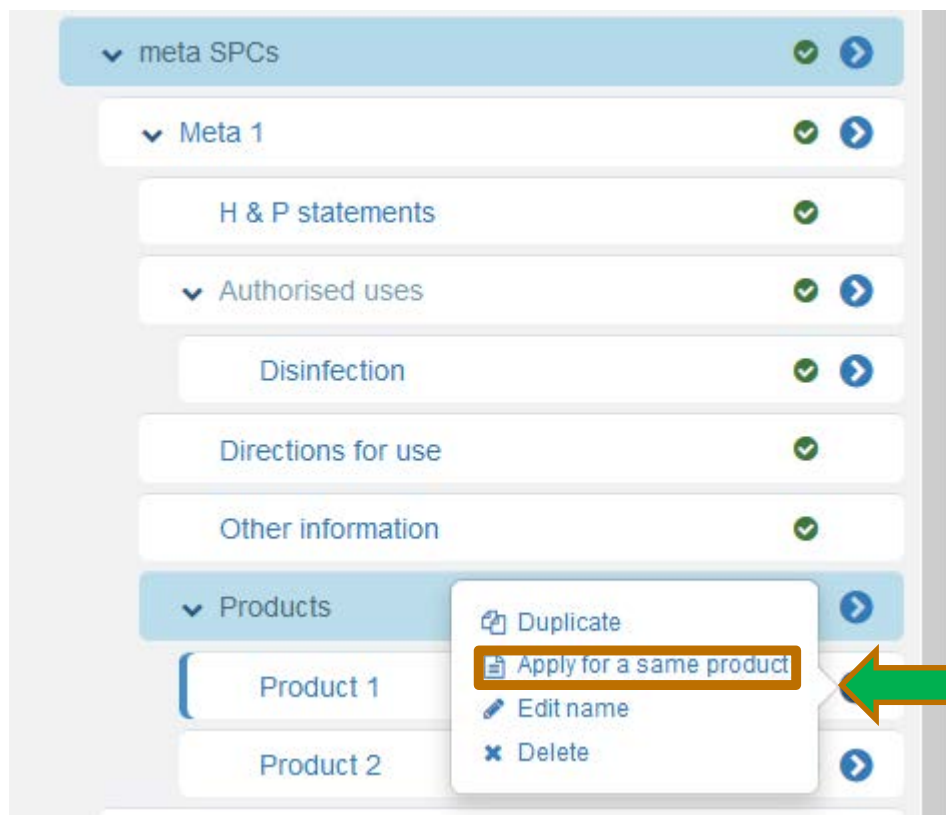
	Hydrogen peroxide		Ethanol		Water		PT
	range	conc	range	conc	range	conc	
<b>Family</b>	<b>20-48%</b>		<b>0.5-1%</b>		<b>51-79.5%</b>		
<b>Meta 1</b>	<b>20-48%</b>		<b>0.5-1%</b>		<b>51-79.5%</b>		<b>2</b>
<b>Product 1</b>		<b>48%</b>		<b>1%</b>		<b>51%</b>	
<b>Product 2</b>		<b>40%</b>		<b>0.5%</b>		<b>59.5%</b>	
<b>Meta 2</b>	<b>20-25%</b>		<b>0.5-0.8%</b>		<b>74.2-79.5%</b>		<b>3</b>
<b>Product 1</b>		<b>20 %</b>		<b>0.5%</b>		<b>79.5%</b>	
<b>Product 2</b>		<b>25%</b>		<b>0.8%</b>		<b>74.2%</b>	

# Create a product family SPC for another market area



The screenshot displays the SPC Editor interface. At the top, a dark blue banner features the ECHA logo and the text "SPC Editor". Below this is a toolbar with buttons for "New", "Open", "Save", "Information", "PDF Preview", and "Import". The "New" button is active, and its dropdown menu is open, showing options: "Product family", "Single product", "Draft from final SPC", "Language version", and "Market area version". The "Market area version" option is highlighted with a brown border. The main workspace shows a table with columns for "Expected", "Test", "Information", and "Product information". The "Test" column contains a dropdown menu with "Test 1" selected. The "Information" and "Product information" rows have green checkmarks in the "Expected" column.

# Create a product family SPC for a same biocidal (single) product



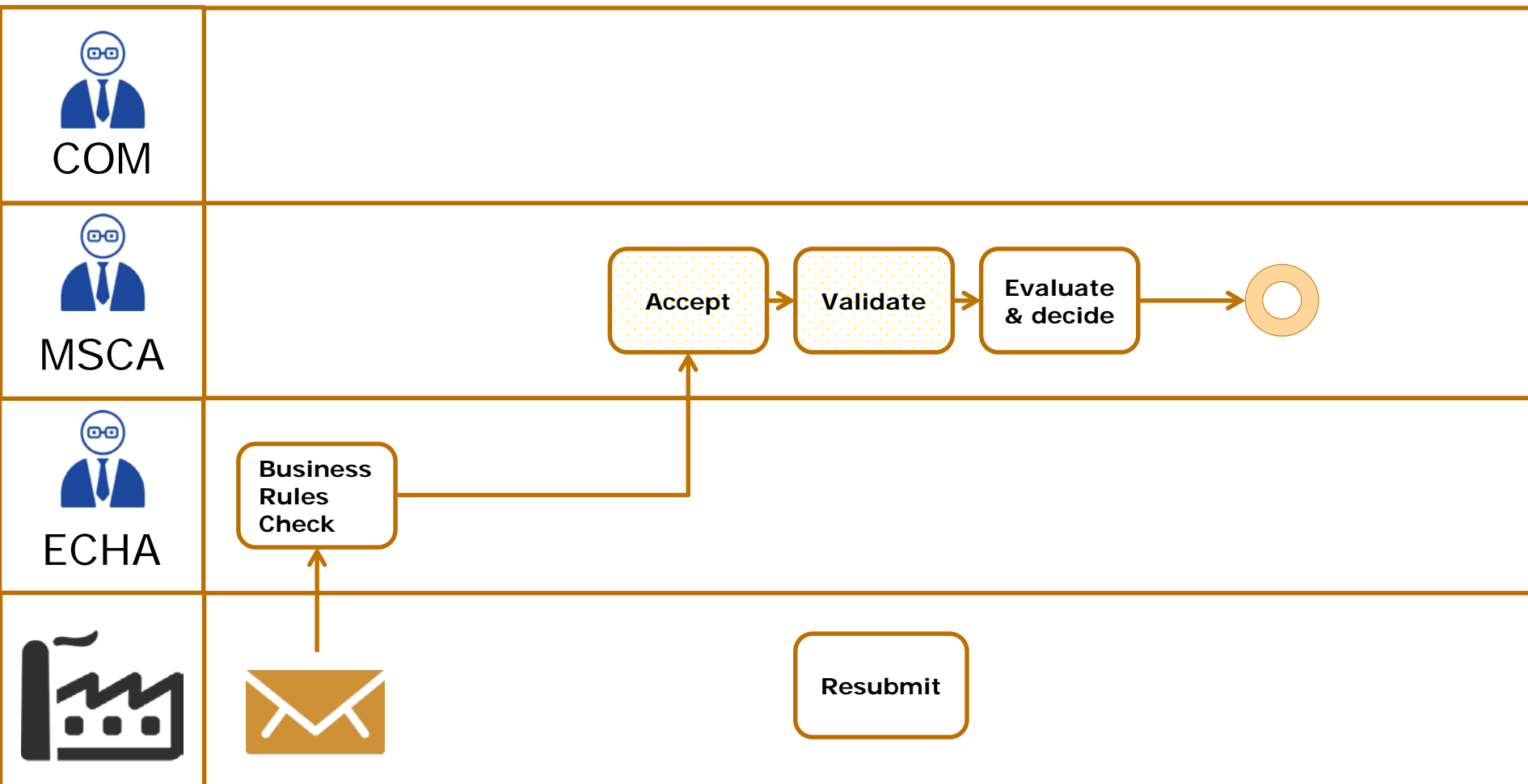
Click here to generate the SPC

## Exercise 2 –NA-APP, NA-MRP (65')

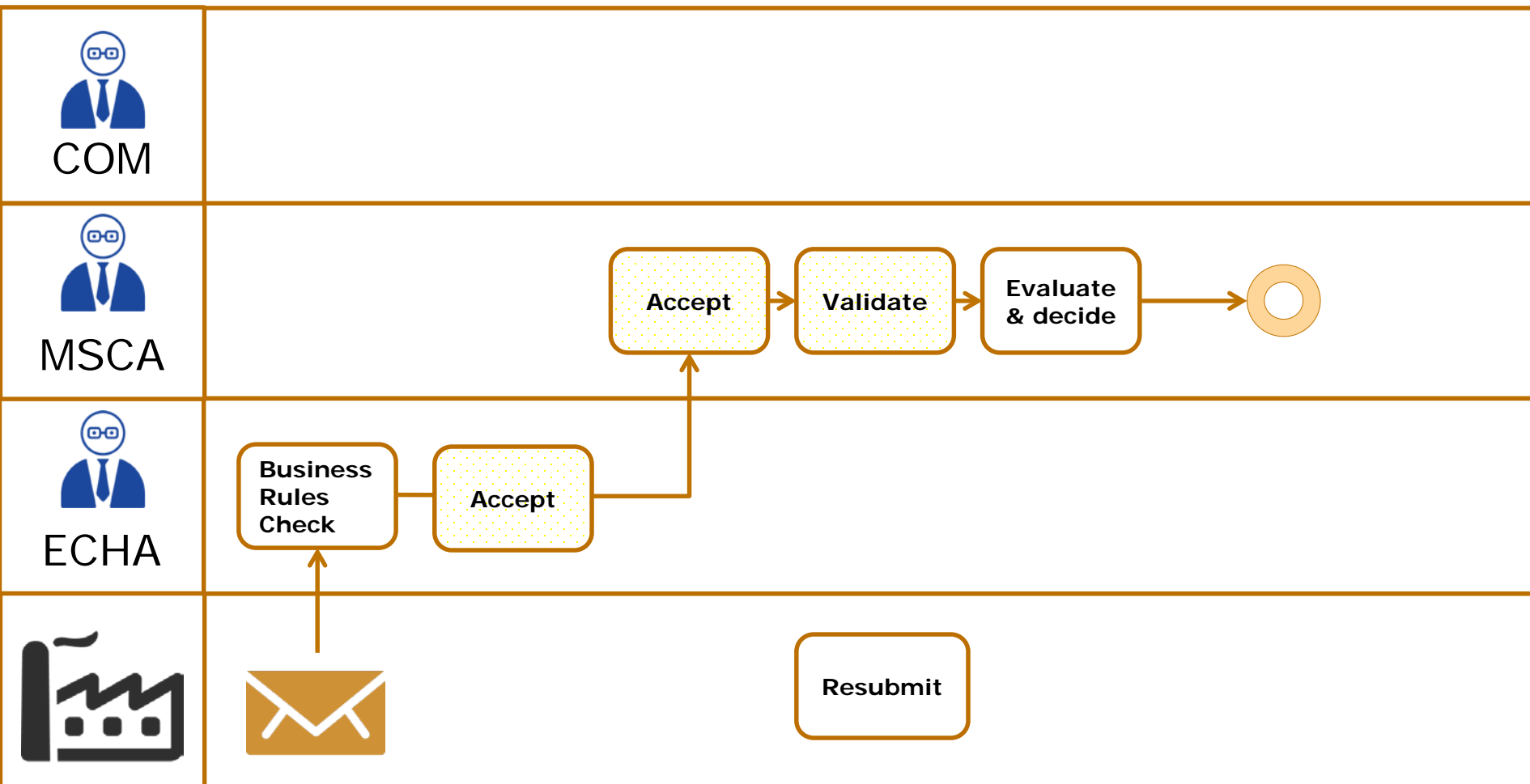




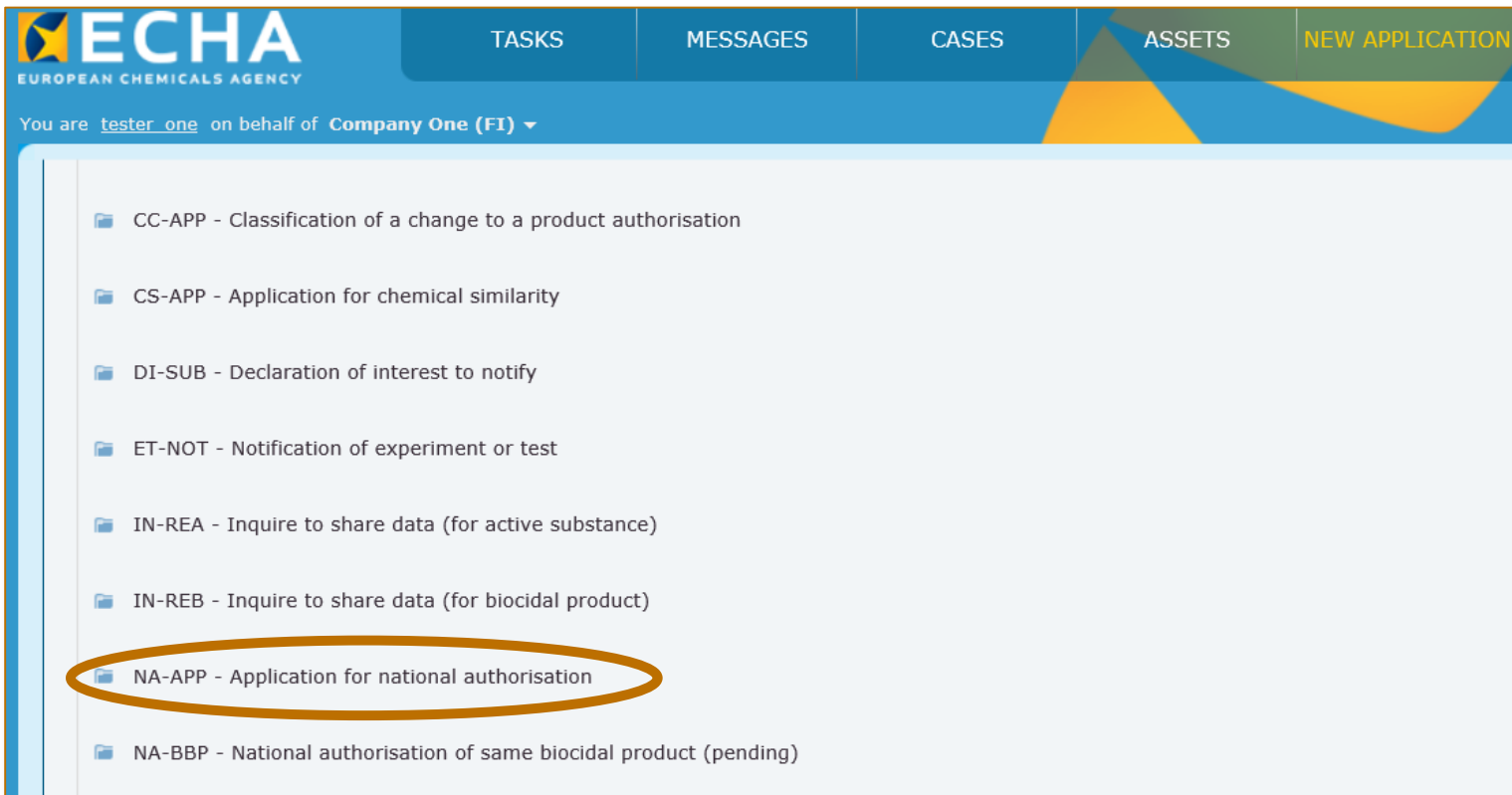
# Workflow: National Authorisation (NA-APP)



# Workflow: Mutual recognition (NA-MRP)



# Apply for National Authorisation



The screenshot displays the ECHA portal interface. At the top, the ECHA logo and name are on the left, and navigation tabs for 'TASKS', 'MESSAGES', 'CASES', 'ASSETS', and 'NEW APPLICATION' are on the right. Below the navigation, a user status bar indicates 'You are tester\_one on behalf of **Company One (FI)**'. The main content area lists several application types, each with a folder icon:

- CC-APP - Classification of a change to a product authorisation
- CS-APP - Application for chemical similarity
- DI-SUB - Declaration of interest to notify
- ET-NOT - Notification of experiment or test
- IN-REA - Inquire to share data (for active substance)
- IN-REB - Inquire to share data (for biocidal product)
- NA-APP - Application for national authorisation**
- NA-BBP - National authorisation of same biocidal product (pending)

# Select authorities

The screenshot shows the ECHA portal interface. At the top, there is a navigation bar with the ECHA logo and the text 'EUROPEAN CHEMICALS AGENCY'. To the right of the logo are two buttons: 'TASKS' and 'MESSAGES'. Below the navigation bar, a user status bar indicates 'You are tester\_one on behalf of **Company One (FI)**'. The main content area is titled 'Submission for application for national authorisation (NA-APP)'. Below this, the section 'Select authorities' is displayed. A message reads: 'Please start the submission process for your application by filling all required information.' The first field is '\*Evaluating authority:' with a dropdown menu currently showing 'Finland'. Below this, a section titled 'If you want to seek mutual recognition, please indicate the relevant Member States from the Concerned Member States:' is shown. A list of Member States is displayed with checkboxes: France, Germany (checked), Greece, Hungary, Iceland, Ireland, Italy, Latvia, and Lithuania. The 'Germany' entry is highlighted with a brown box.




# Upload IUCLID 6 dossier

Submission for application for national authorisation (NA-APP)

## Upload dossier

Please upload below your file which contains your dossier (your file should have been created using IUCLID 6 and have an extension .i6z). Please make sure that you don't upload encrypted/password protected files.

Dossier   

File names should not contain special characters 



**Make sure it is a IUCLID 6 dossier !**








# Upload all relevant SPCs


Submission for application for national authorisation (NA-APP)

## Upload SPC

Please upload below your SPC (summary of product characteristics) file that is required for your application.

\*Please upload the necessary SPC file(s)

	DE-Germany	FI-Finland
	<input checked="" type="radio"/> en 	<input type="radio"/> en 
Test11 	 	 

File names should not contain special characters 

# Submit application

Submission for application for national authorisation (NA-APP)

## Your next steps

**Your submission numbers are:**

**Reference Case:**

BC-BR001344-46/1 (MSCA-Germany)


**Concerned Case(s):**

BC-FA001345-74/1 (MSCA-Finland)

**Note that receipt of this message does not guarantee that your**


1. If your application is in the correct format you will receive a mes
  2. Monitor your application progress in the "Events History" tab un
- If you need to contact the ECHA Helpdesk regarding your application p


# ECHA – Business rules check for case 1 and 2

 **BRC confirmation** TASK-1742402

**Task details**



Task name: BRC confirmation  
Task number: TASK-1742402  
Created on: 12/09/2017      Status: **Unclaimed**  
Claimed by: not claimed yet      Claimed on: -





Due date:  **14/09/2017**



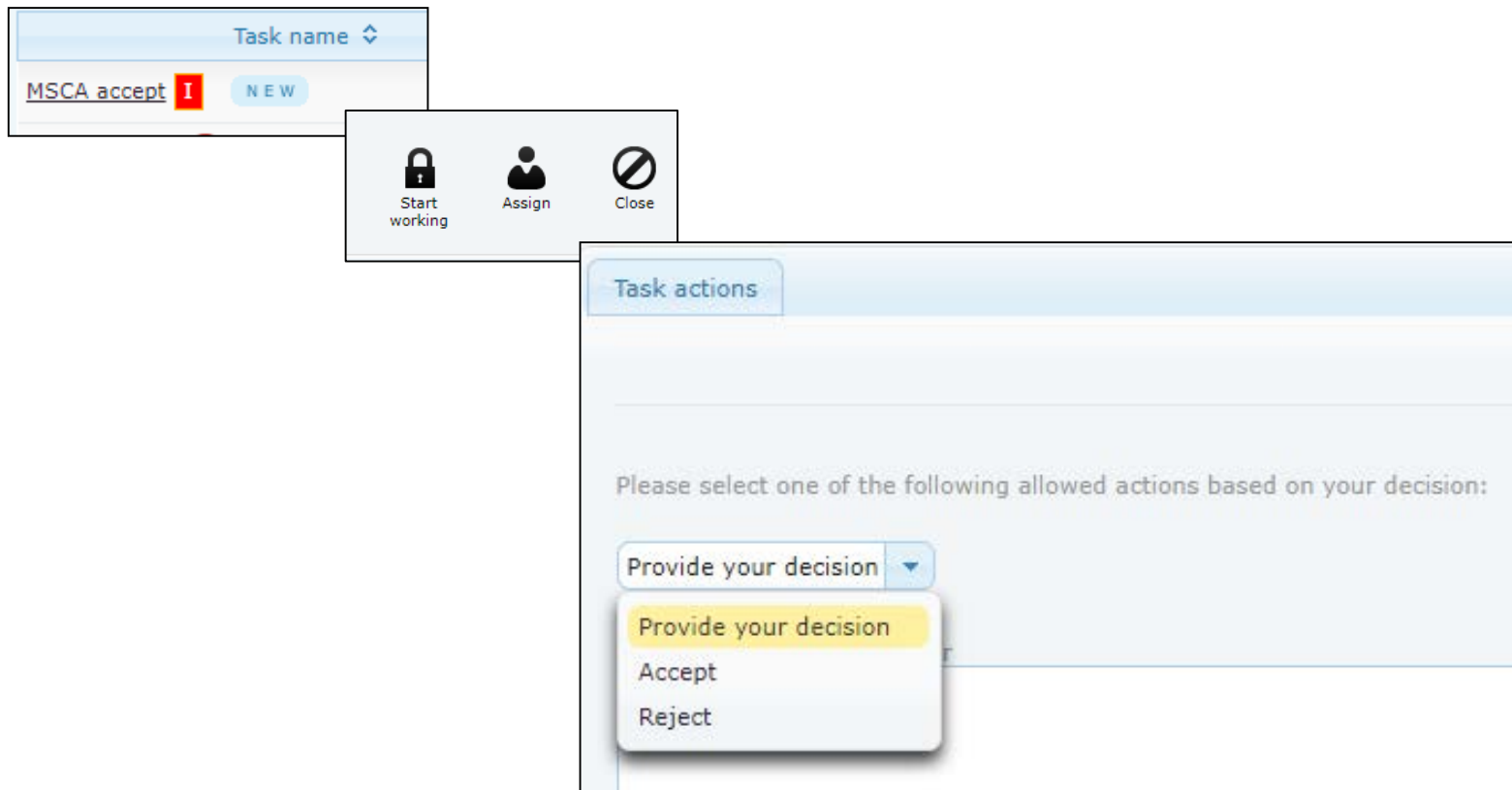
Task history

---

 **Start working**       **Close**

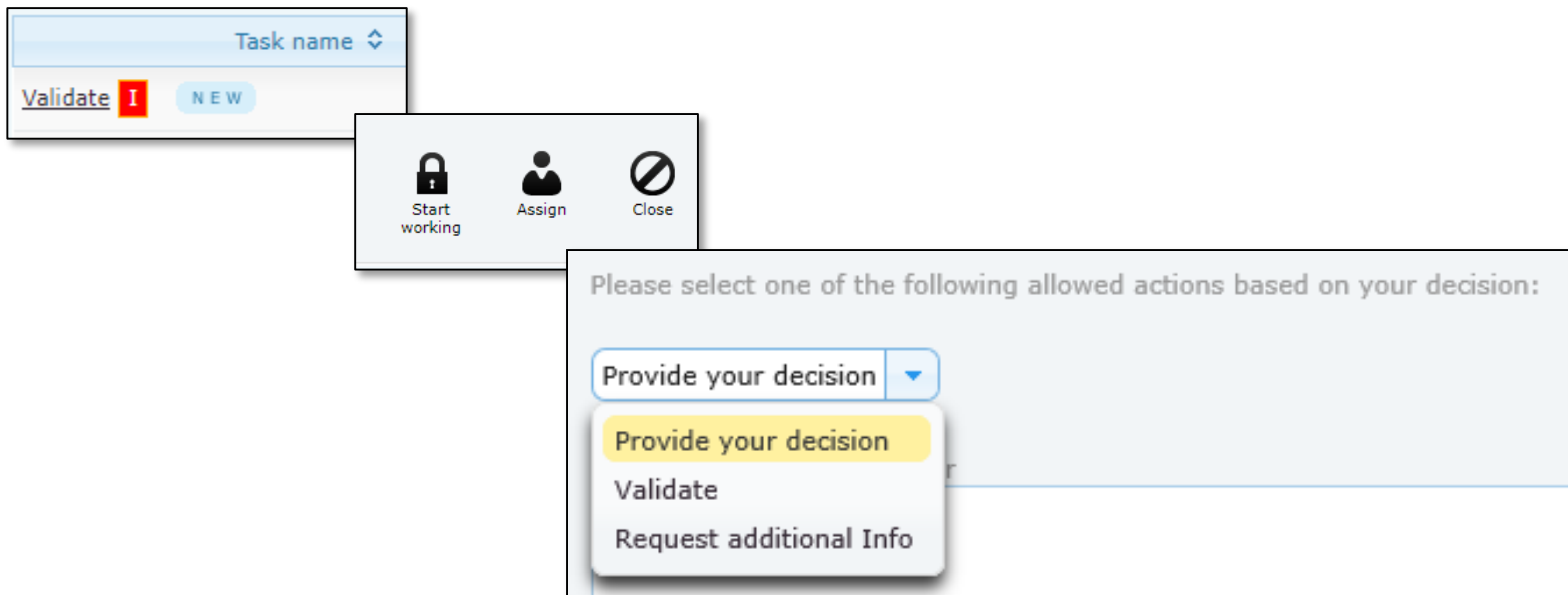
 **Complete**       **Save**       **Release**       **Close**

# MSCA – Accept for case 1 and 2



The screenshot displays a task management interface. At the top left, a task card is visible with the title "Task name" and a dropdown arrow. Below the title, the task name "MSCA accept" is shown next to a red status indicator "I" and a blue "NEW" button. To the right of the task card is a vertical menu with three options: "Start working" (with a lock icon), "Assign" (with a person icon), and "Close" (with a prohibition sign icon). Below the menu is a large panel titled "Task actions". Inside this panel, there is a text prompt: "Please select one of the following allowed actions based on your decision:". Below the prompt is a dropdown menu labeled "Provide your decision" with a downward arrow. The dropdown menu is open, showing three options: "Provide your decision" (highlighted in yellow), "Accept", and "Reject".

# MSCA – Validate for case 1 and 2

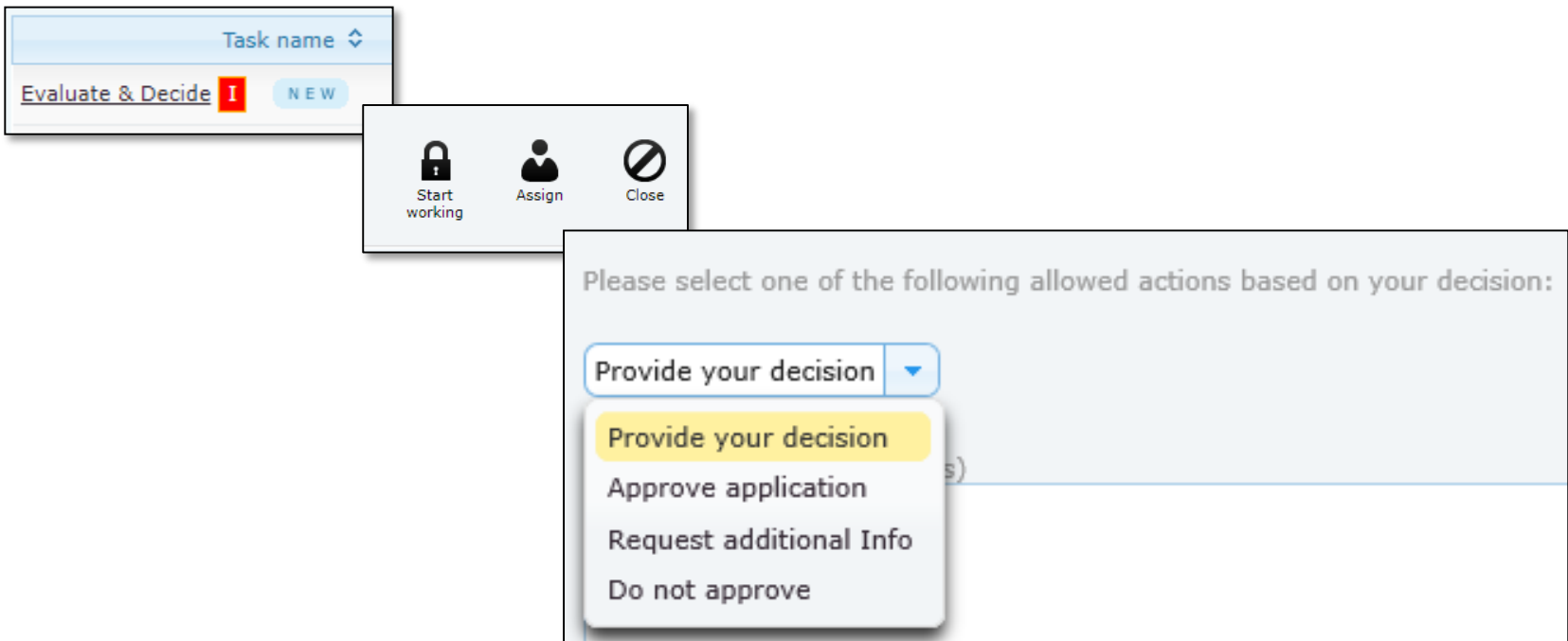


The screenshot displays a user interface for task management. At the top left, there is a dropdown menu labeled "Task name" with a downward arrow. Below it, the word "Validate" is shown next to a red square icon containing a white letter "I", followed by a light blue button labeled "NEW".

In the center, a panel contains three icons: a padlock labeled "Start working", a person icon labeled "Assign", and a circle with a diagonal slash labeled "Close".

At the bottom right, a larger panel is titled "Please select one of the following allowed actions based on your decision:". It features a dropdown menu currently set to "Provide your decision". A list of options is shown below the dropdown: "Provide your decision" (highlighted in yellow), "Validate", and "Request additional Info".

# MSCA – Evaluate for case 1 and 2



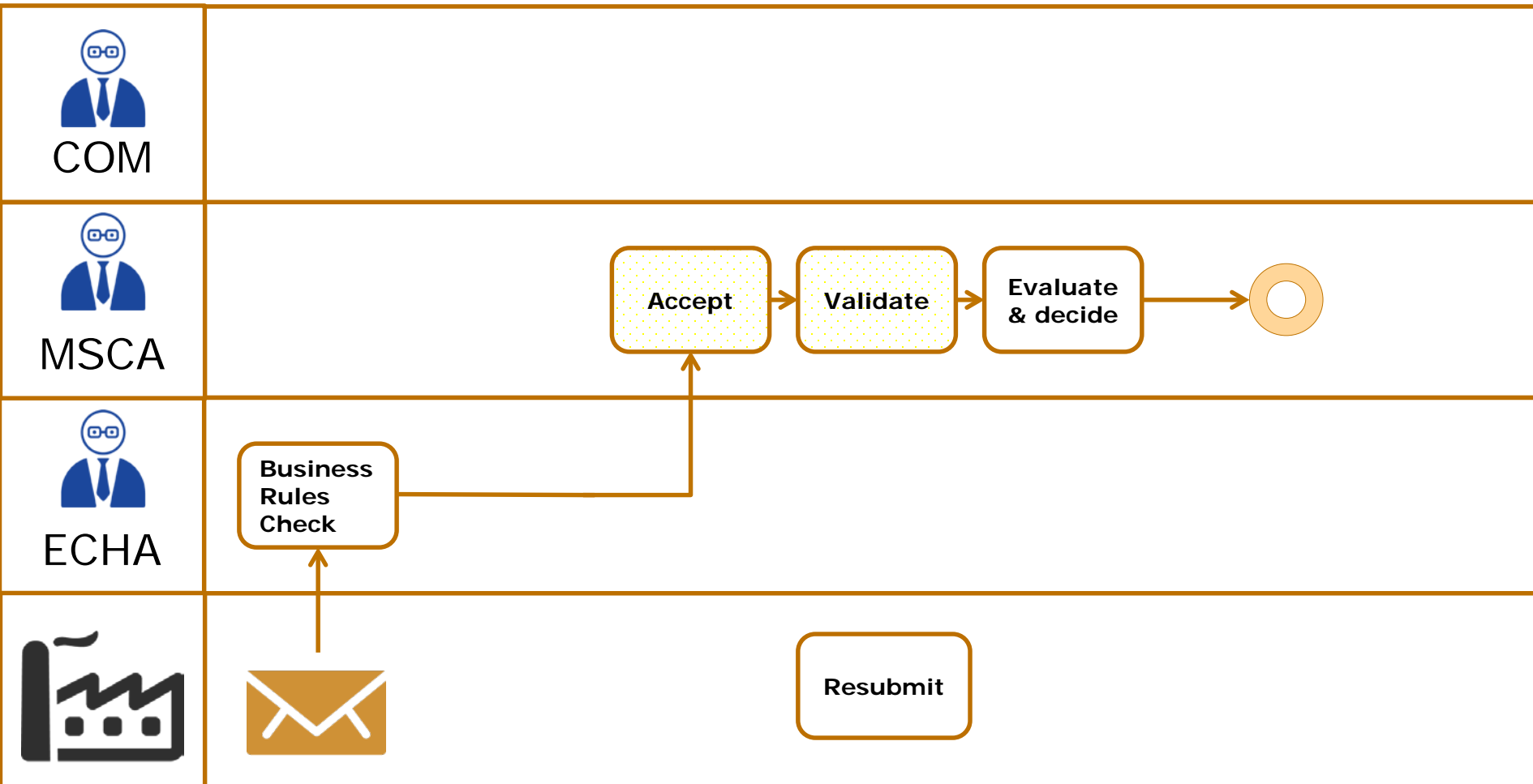
The screenshot displays the MSCA evaluation interface. At the top left, a task card is visible with the text "Task name" and a dropdown arrow. Below it, the task name "Evaluate & Decide" is shown with a red information icon and a "NEW" button. In the center, there are three action buttons: "Start working" (with a lock icon), "Assign" (with a person icon), and "Close" (with a slash icon). On the right, a large panel contains the instruction "Please select one of the following allowed actions based on your decision:". Below this instruction is a dropdown menu currently set to "Provide your decision". The dropdown menu is open, showing four options: "Provide your decision" (highlighted in yellow), "Approve application", "Request additional Info", and "Do not approve".

## Exercise 3 – Apply for NA-BBS (20')





# Workflow: National Authorisation of Same Biocidal Product (NA-BBS)



# Apply for Same Biocidal Product

- NA-APP - Application for national authorisation
- NA-BBP - National authorisation of same biocidal product (pending)
- NA-BBS - National authorisation of same biocidal product (authorised)

## Set reference details

*Please provide below your reference number (asset)*

\* Reference asset number:

# Collect the Case number

## Your next steps

**Submission number** BC-LU002857-12/1

**Note that receipt of this message does not guarantee that your application is accepted for processing.** Verification of the format must first be completed by R4BP 3, therefore it is important that you follow the advice below in case further action (such as a resubmission) is required from you.

1. If your application is in the correct format you will receive a message in your R4BP 3 message tab with further instructions. If your **application is not in the correct format you will receive a task item with instructions on how to resubmit a new one.** Please pay attention to the resubmission deadline.
2. Monitor your application progress in the "Events History" tab under the case details page.

If you need to contact the ECHA Helpdesk regarding your application please provide the submission number.

Close

# Process the application

MSCA accept **I** NEW

Validate **I** NEW

Please select one of the following allowed actions based on your decision:

Provide your decision ▾

Provide your decision

Validate

Request additional Info

Evaluate & Decide **I** NEW

Please select one of the following allowed actions based on your decision:

Provide your decision ▾

Provide your decision

Approve application

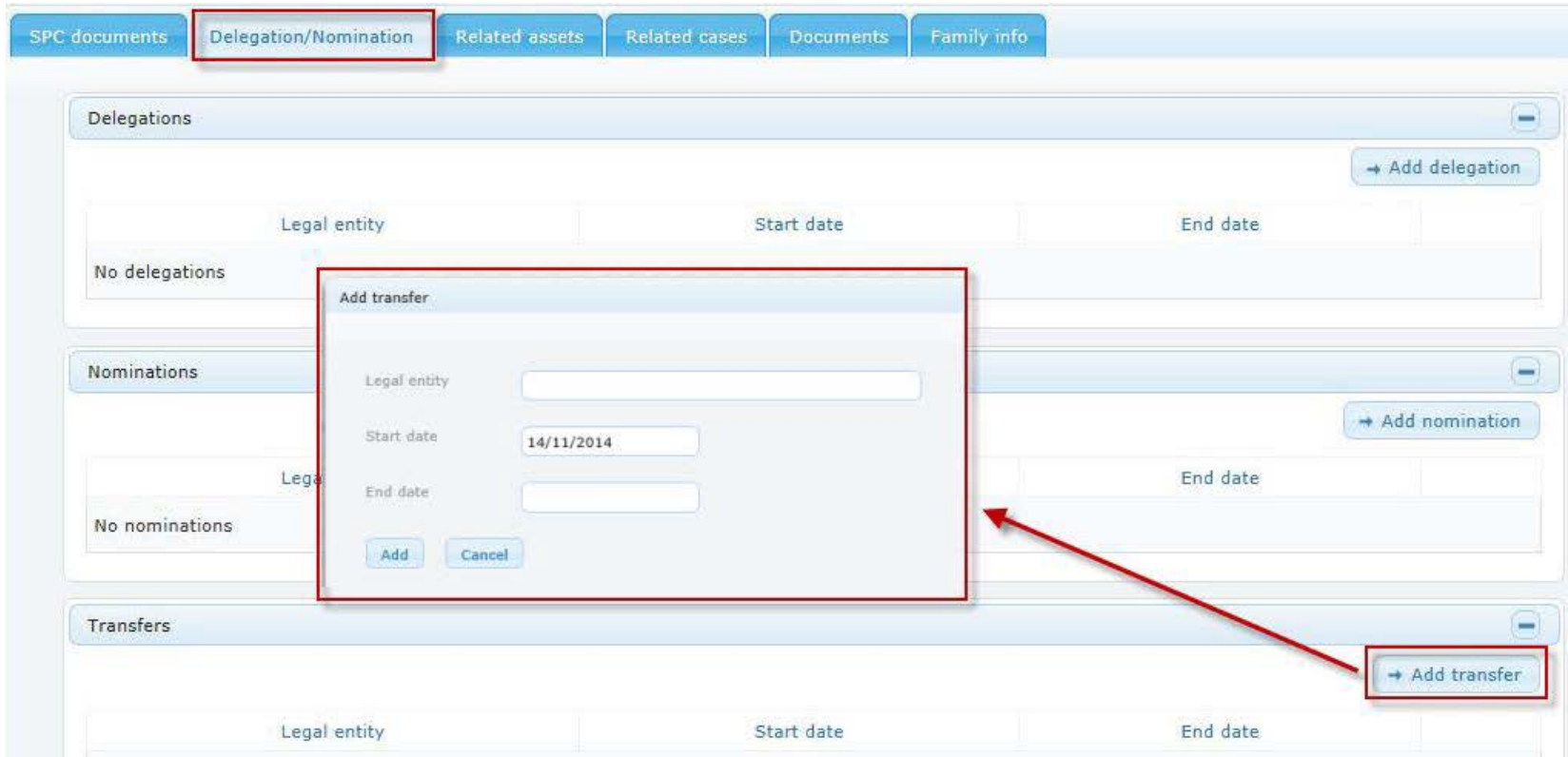
Request additional Info

Do not approve

## Exercise 4 – Transfer an asset (optional)



# Add asset transfer



The screenshot displays the ECHA SPC system interface. At the top, there are navigation tabs: "SPC documents", "Delegation/Nomination" (highlighted with a red box), "Related assets", "Related cases", "Documents", and "Family info". Below the tabs, there are three main sections: "Delegations", "Nominations", and "Transfers". Each section has a table with columns for "Legal entity", "Start date", and "End date". The "Delegations" section shows "No delegations" and an "Add delegation" button. The "Nominations" section shows "No nominations" and an "Add nomination" button. The "Transfers" section shows "No transfers" and an "Add transfer" button (highlighted with a red box). A modal window titled "Add transfer" is open, containing input fields for "Legal entity", "Start date" (with the value "14/11/2014"), and "End date", along with "Add" and "Cancel" buttons. A red arrow points from the "Add transfer" button in the "Transfers" section to the modal window.

# Accept asset transfer

National authorisation (NA): DE-0011688-0000

Asset status: Active

Market area: Germany

Valid from: 25/05/2016

To: 25/05/2026

Source case number: BC-YT005452-16

Other reference number: DE-0011688-00-0000-02

## Product Information

Family name: Bref Power Toilet Cleaner - Biocidal Product Family

Product type(s): 2

Active substance(s): • Hydrochloric acid

## Asset owner

Company name: CI-Manuals

Company UUID: ECHA-7728e530-de83-4cf7-a5e2-a9ee30e40dfa

Create new case



Accept Asset Transfer