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

Biocides Stakeholders' day IT training

27 September 2017

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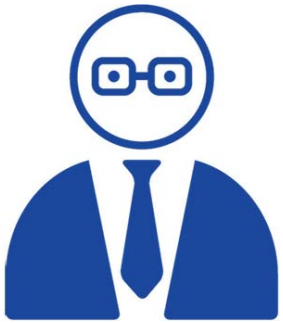
European Chemicals Agency

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…

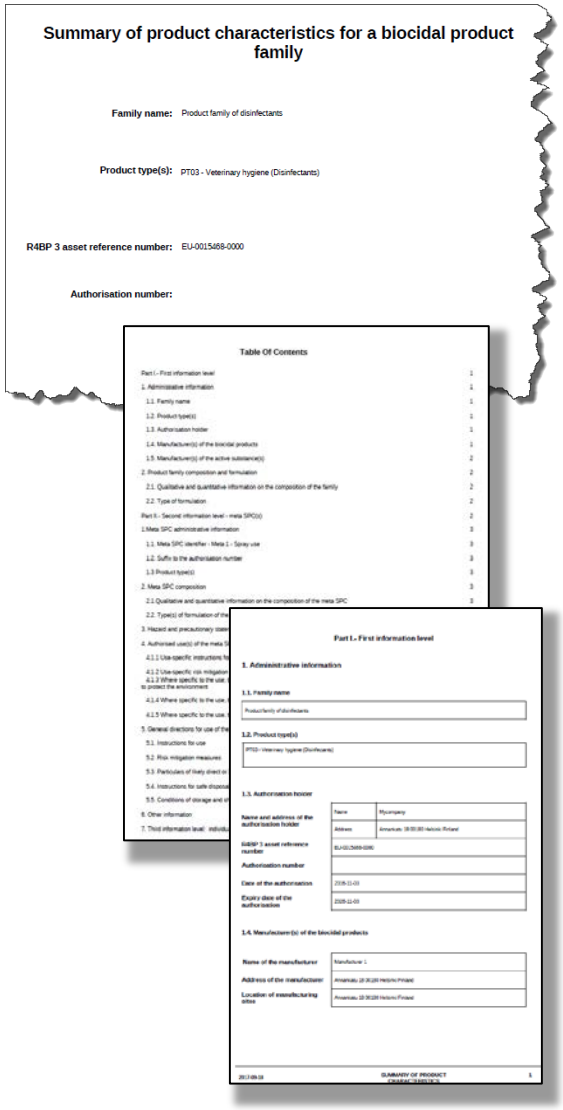
- Introduce the basics of R4BP 3 and SPC editor
- Show you how to use them to get your required authorisation by:
  - ✓ Guiding you in a role-play where you will prepare the SPCs and perform the applications in R4BP 3
  - ✓ Demonstrating how Competent Authorities are recording their evaluations
- Summarise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



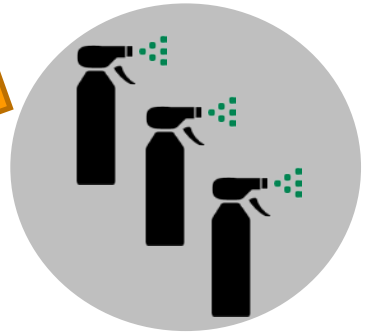
How to prepare it?

- To be filled in electronic format

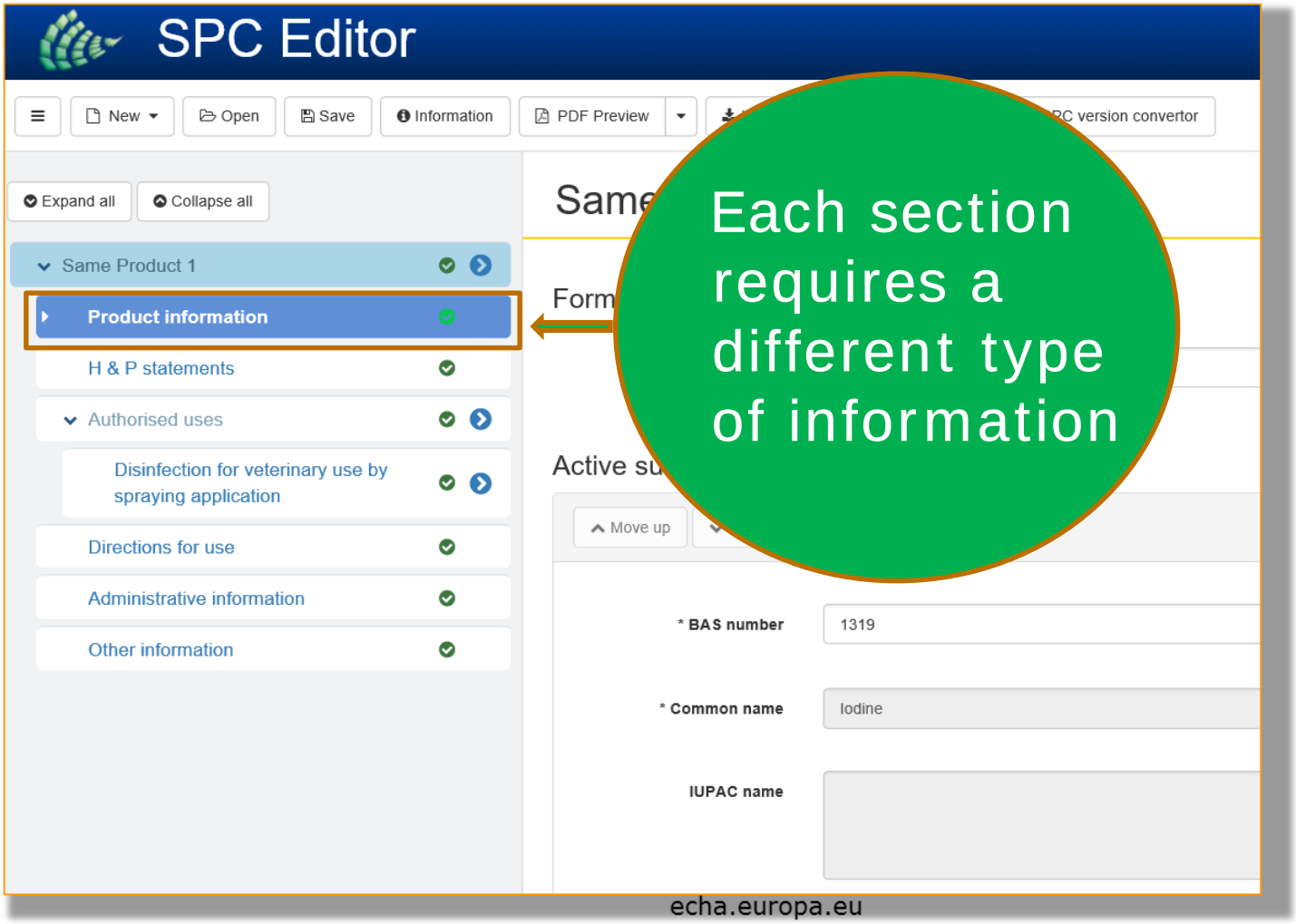
SPC editor

- The information requirements are different for:
  - ✓ Single products
  - ✓ Product families

- Used for:
  - ✓ R4BP 3 data processing
  - ✓ Dissemination
  - ✓ Comparison



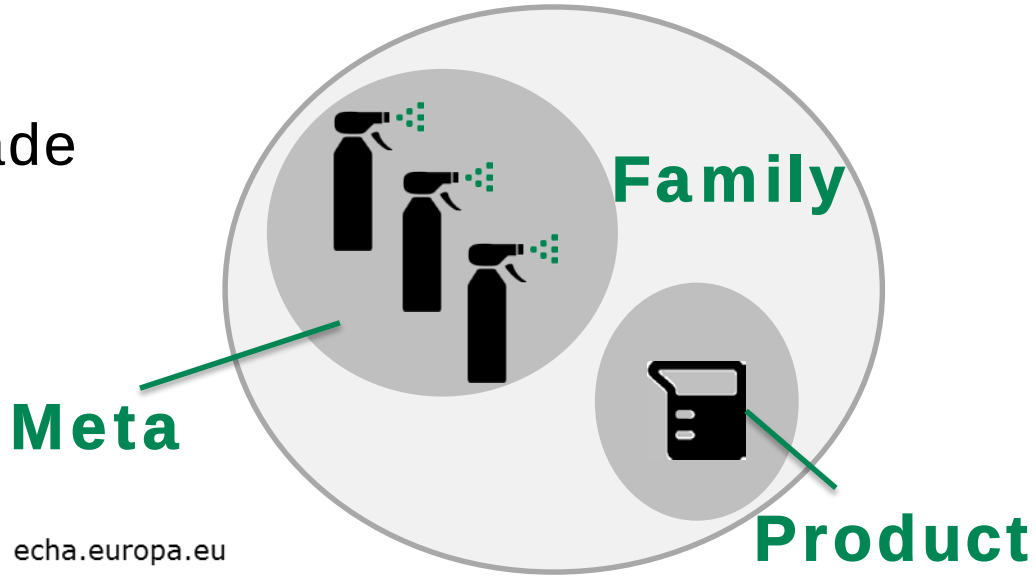
SPC user interface for single product



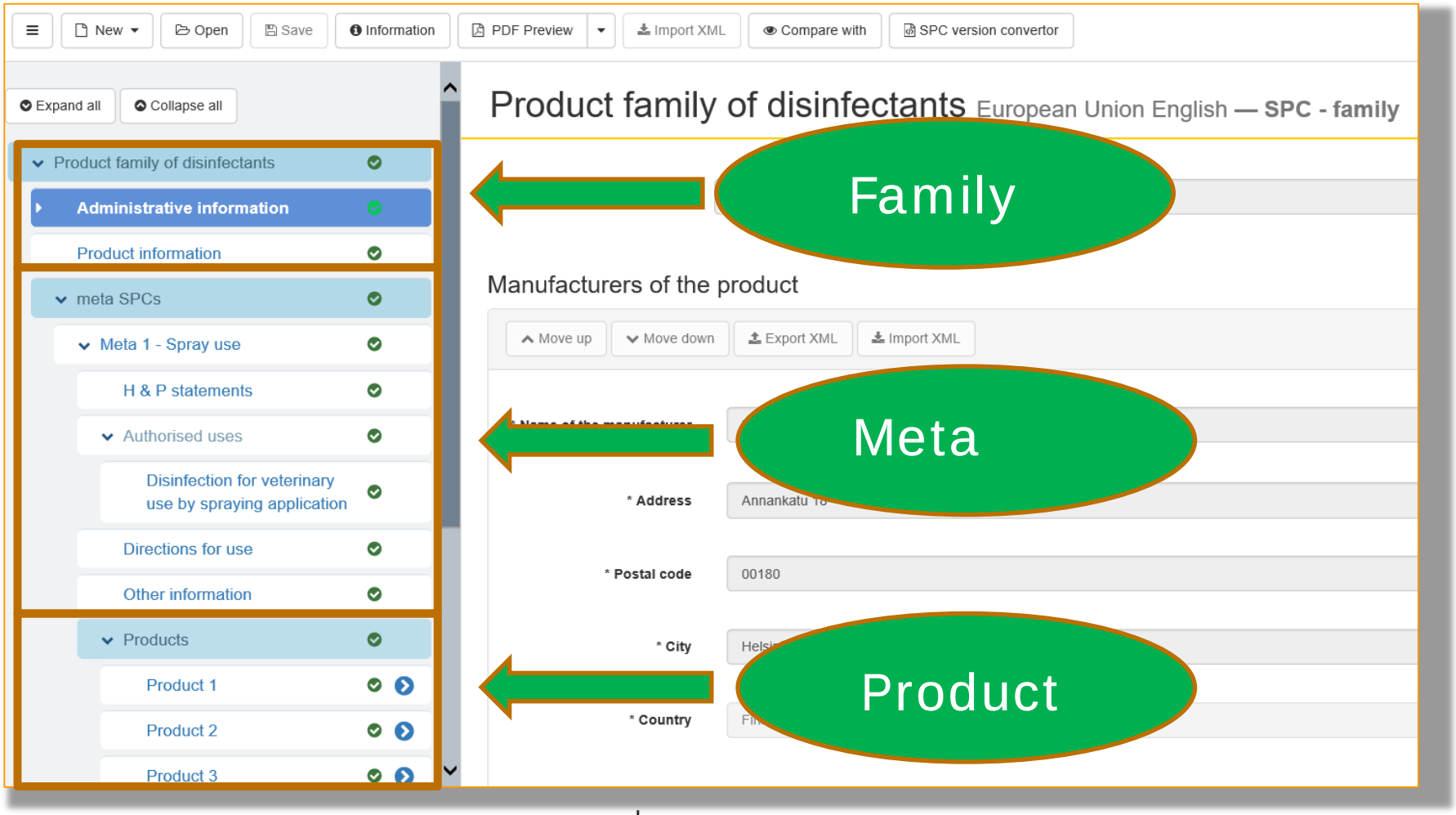
Product Family SPC

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

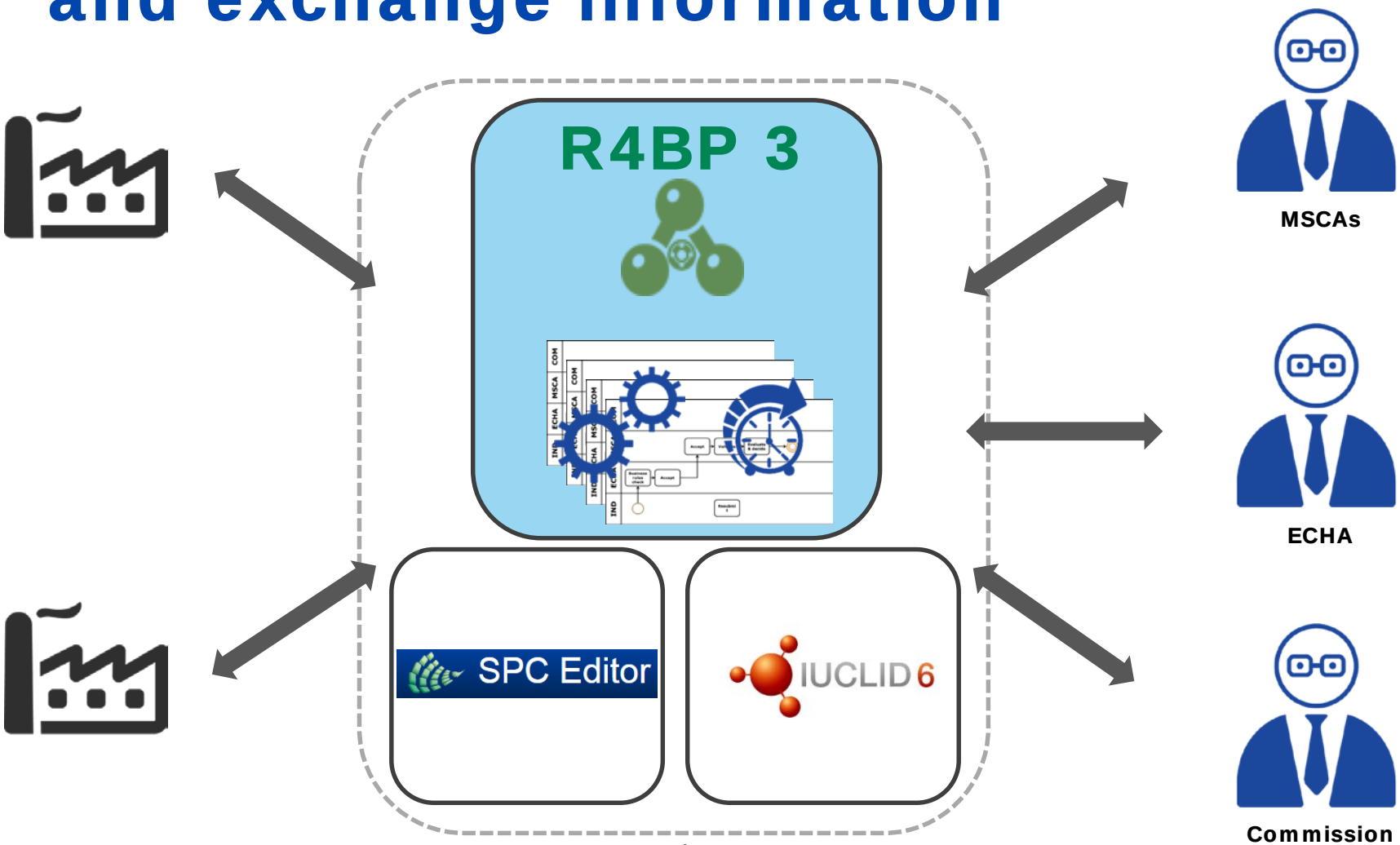


Today your task is to create…

- 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

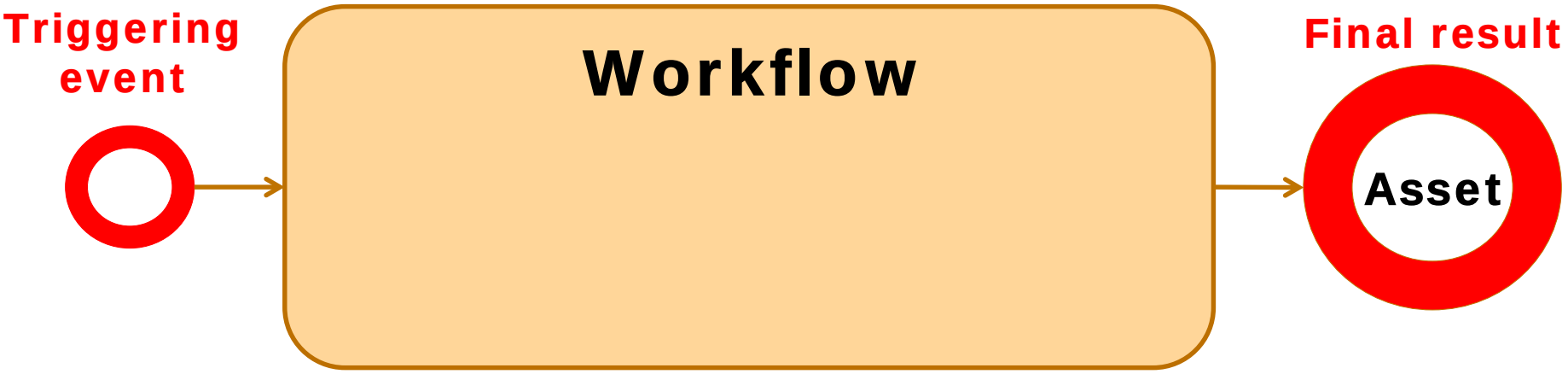
Central hub to comply with legislation and exchange information



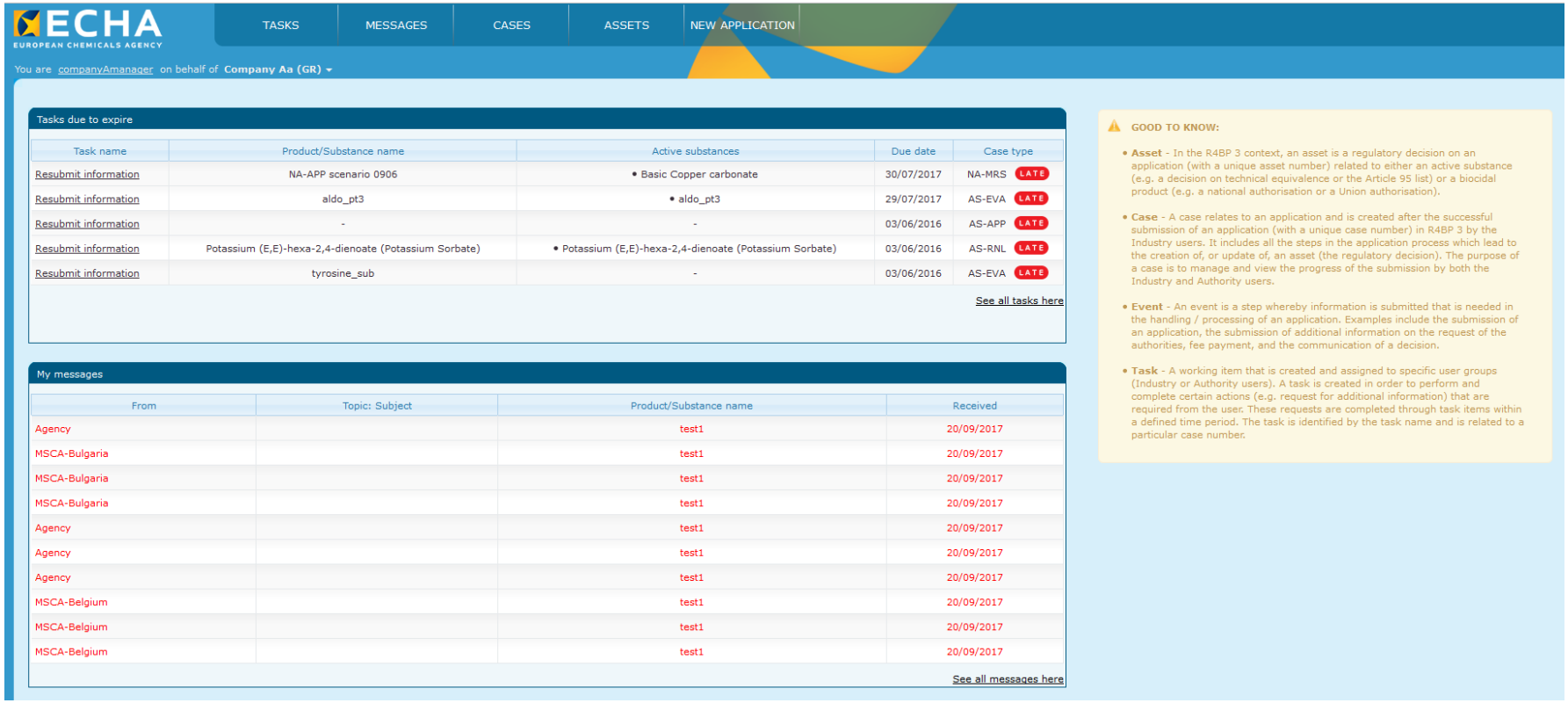
BPR processes

- 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

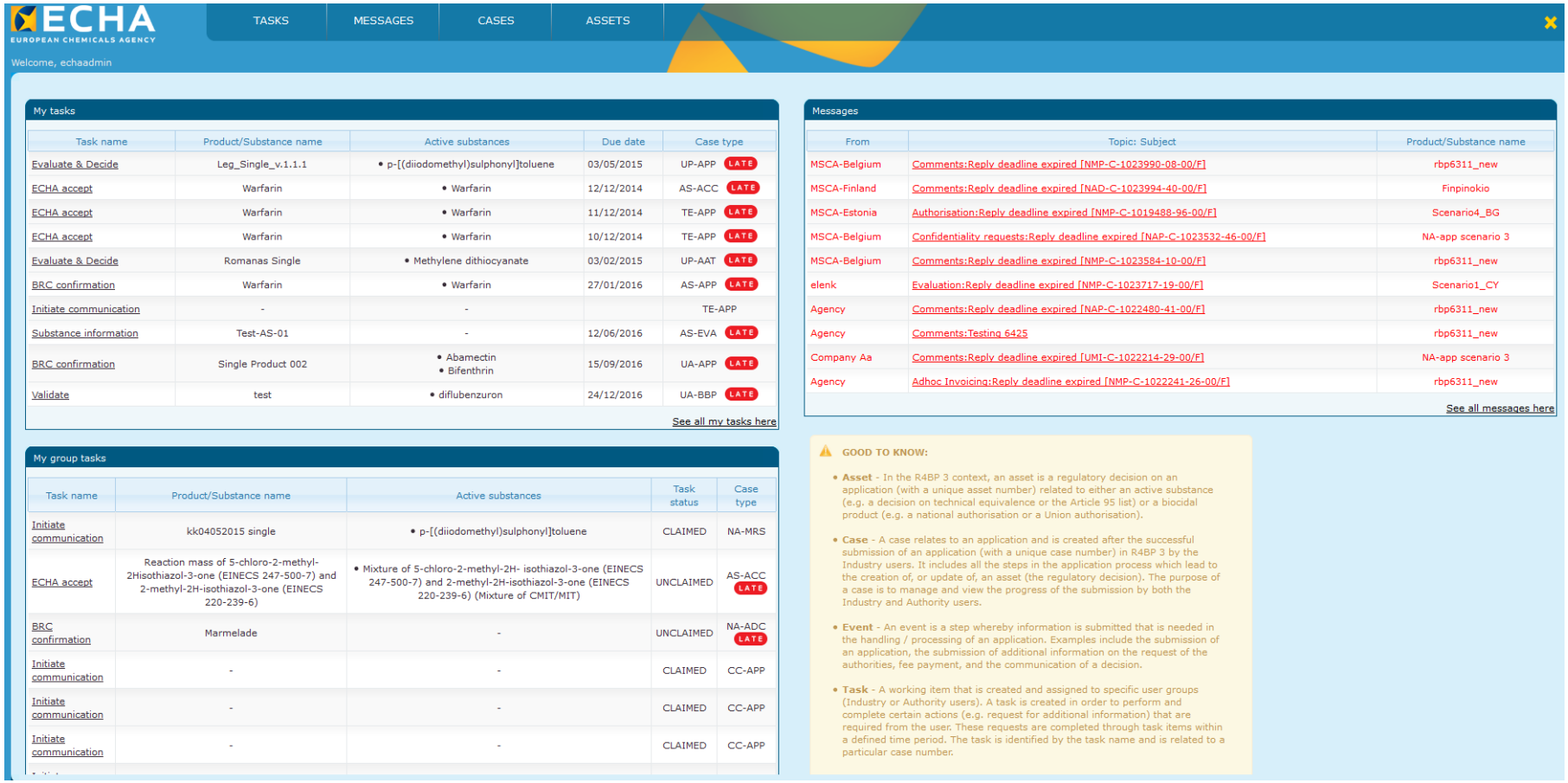
BPR processes as IT workflows



R4BP 3 User Interface (IND)

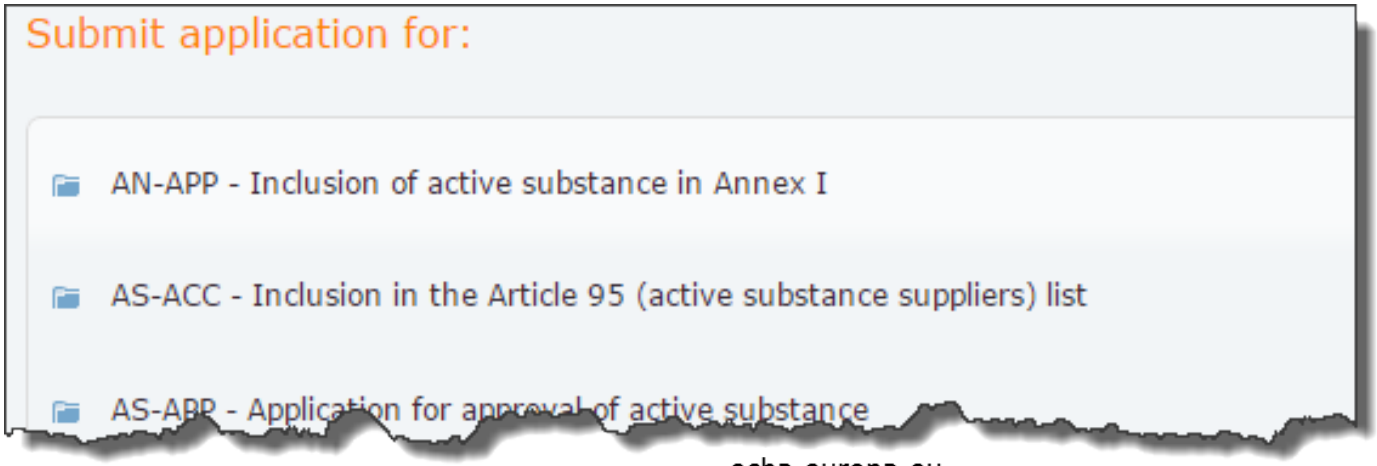


R4BP 3 User Interface (AUTH)



Triggering event: new Application

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



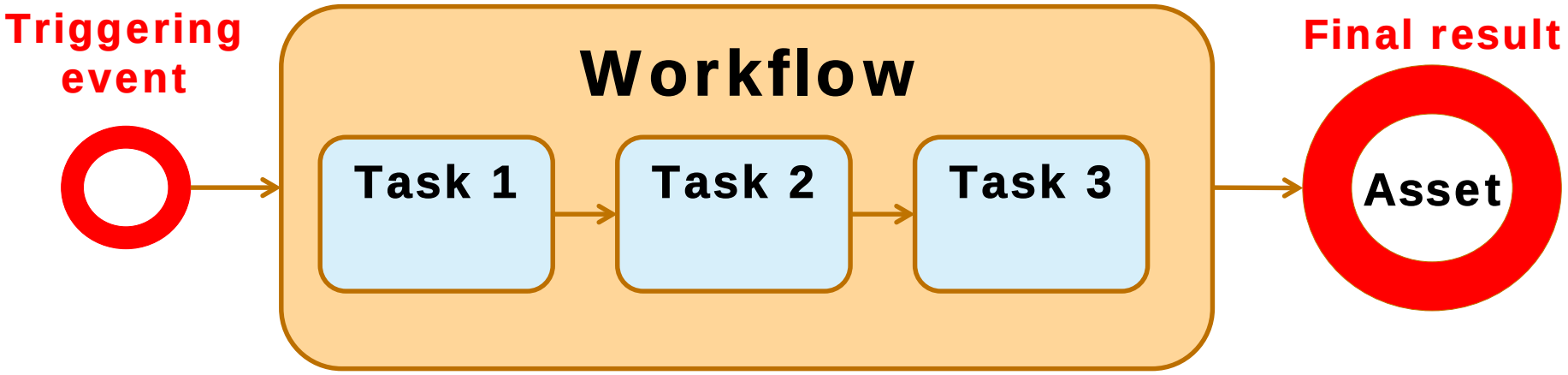
Assets

- Positive outcome on an application
- Unique asset number

Assets list

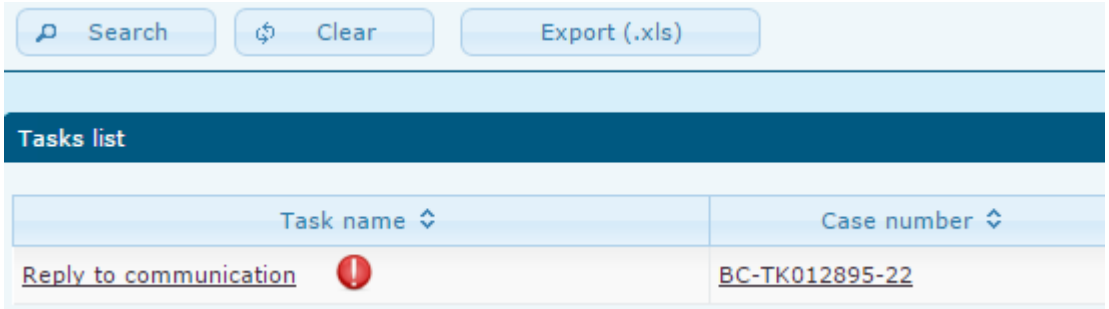
Asset number	Product/Substance name	Active substances	Asset type
DE-0003841-0000 D	asdf	• Methylene dithiocyanate	NA
DE-0000505-0000	Warfarin	• Warfarin	ET

Process steps as workflow tasks

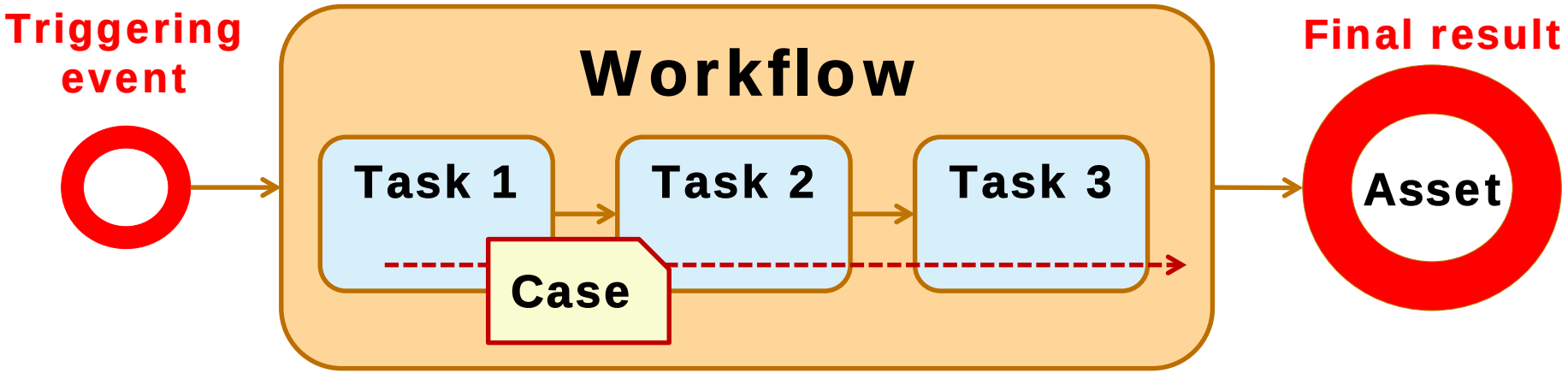


Tasks – You are required to act

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



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 [NMP-C-1079424-06-00/F]
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 [NMP-C-1079421-09-00/F]
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 [BC-WY012898-85/1]

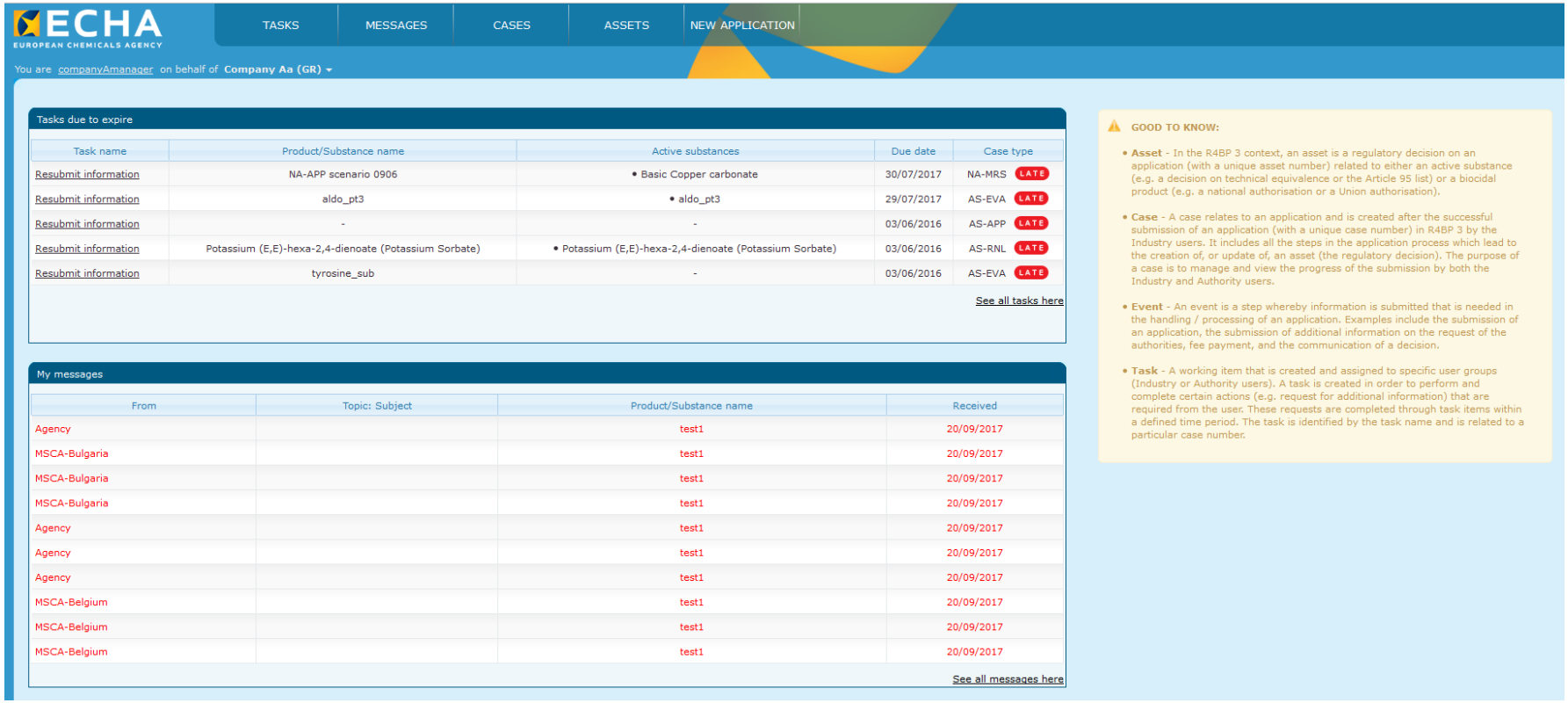
Messages – Your Communication

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

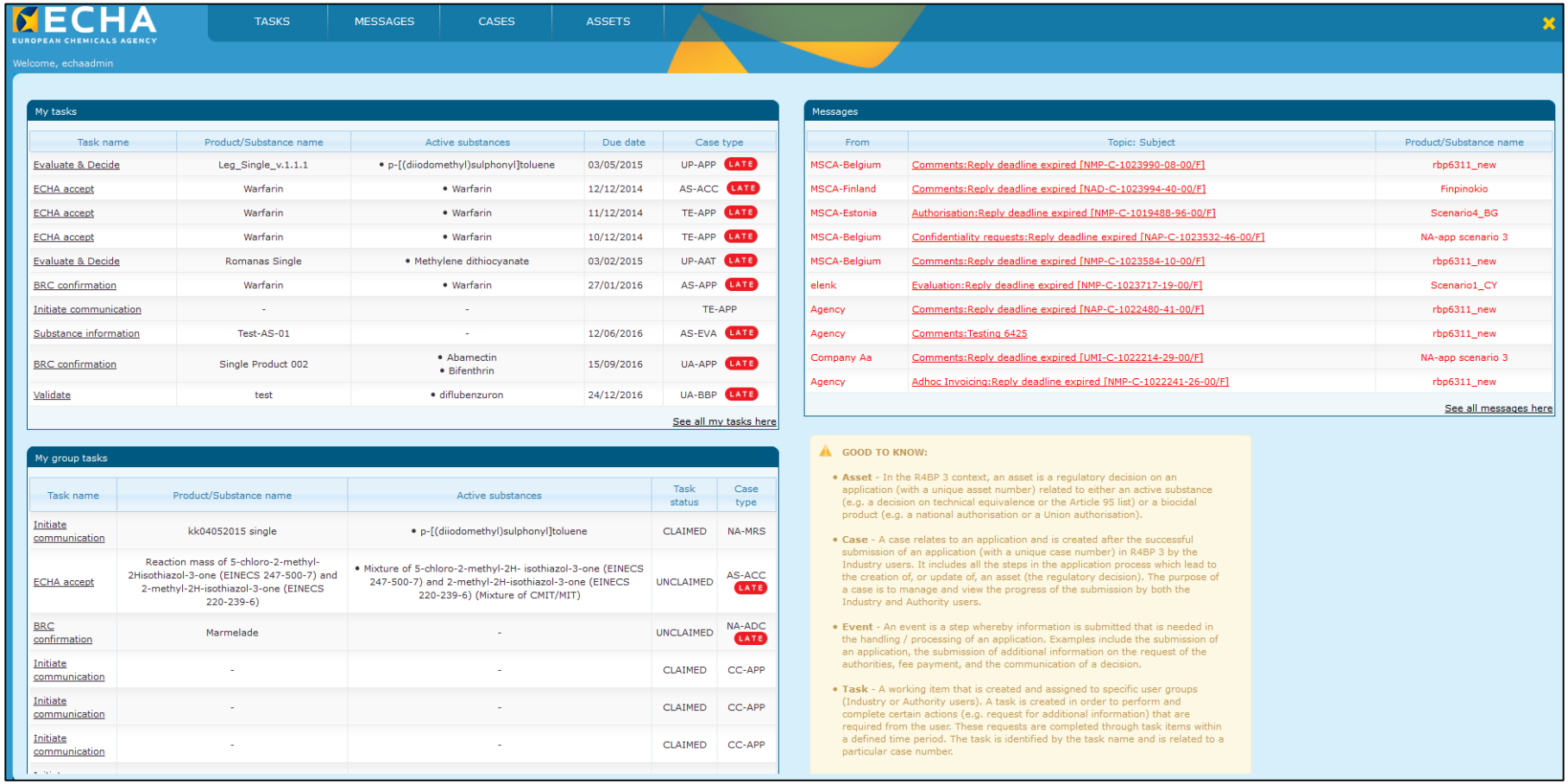
Message list

From	Topic: Subject
Agency	Submission:Submission accepted by ECHA [NMP-C-1079424-06-00/F]
Agency	Format Checks:Submission format verified [NMP-C-1079420-10-00/F]
Agency	Format Checks:Submission format verified [NMP-C-1079422-08-00/F]

R4BP 3 User Interface (IND)



R4BP 3 User Interface (AUTH)



Role play

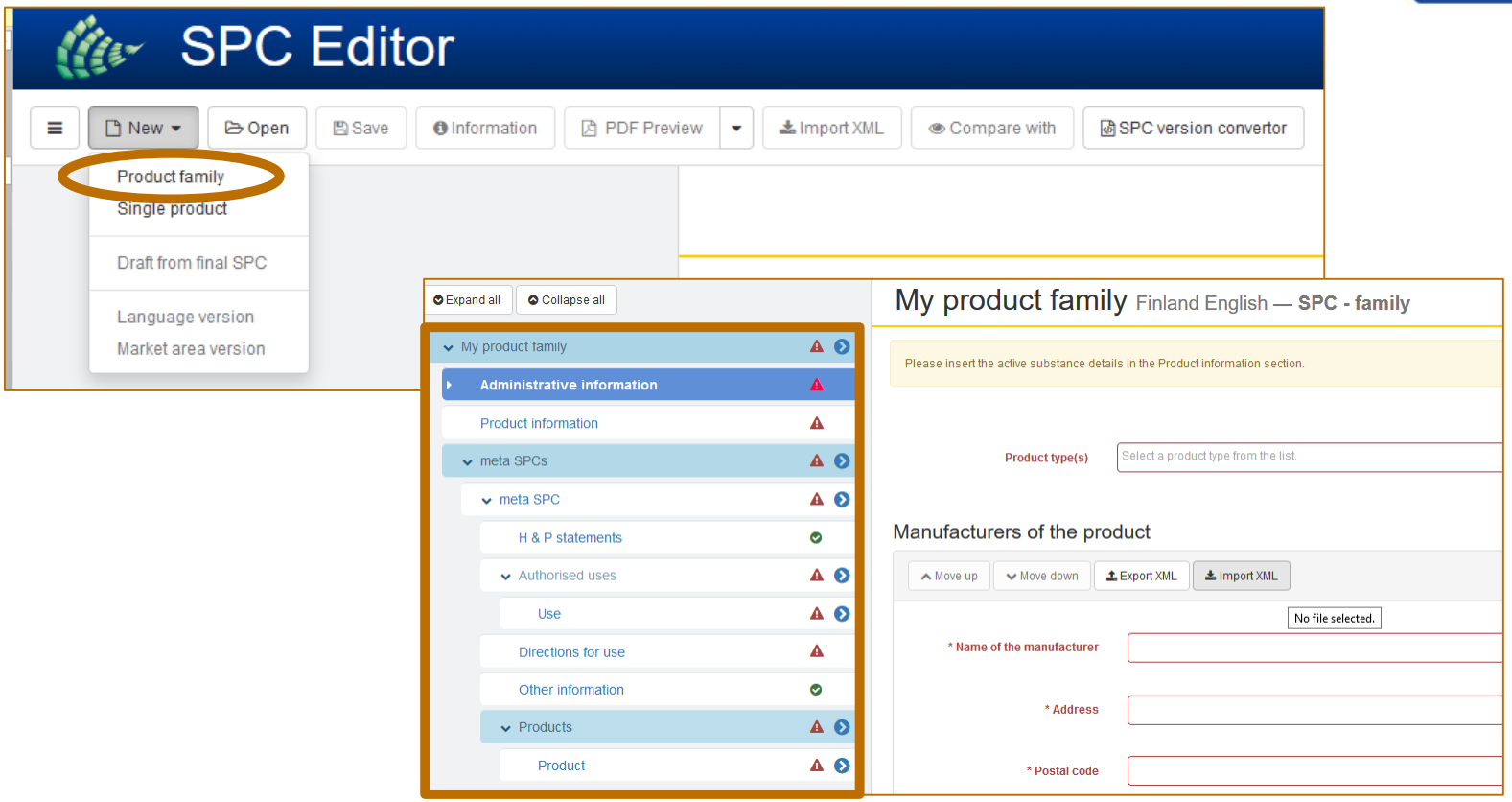
Let’s get the authorisations!

- 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!

R4BP 3 and SPC editor hands-on session	
	27 September 2017
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	**END**

Exercise 1 – Create SPCs (40’)

Create a product family SPC

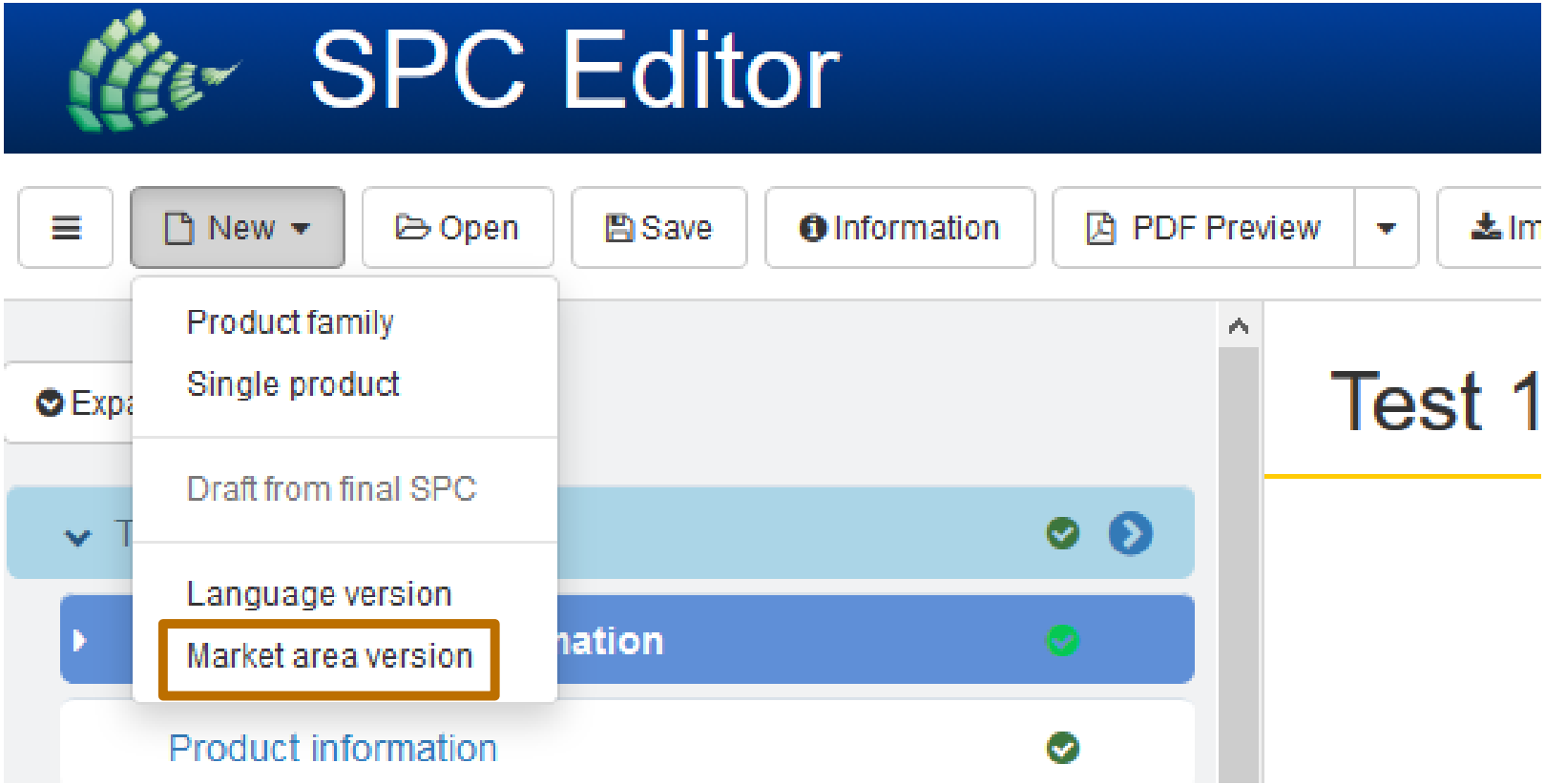


SPC information for your Product family

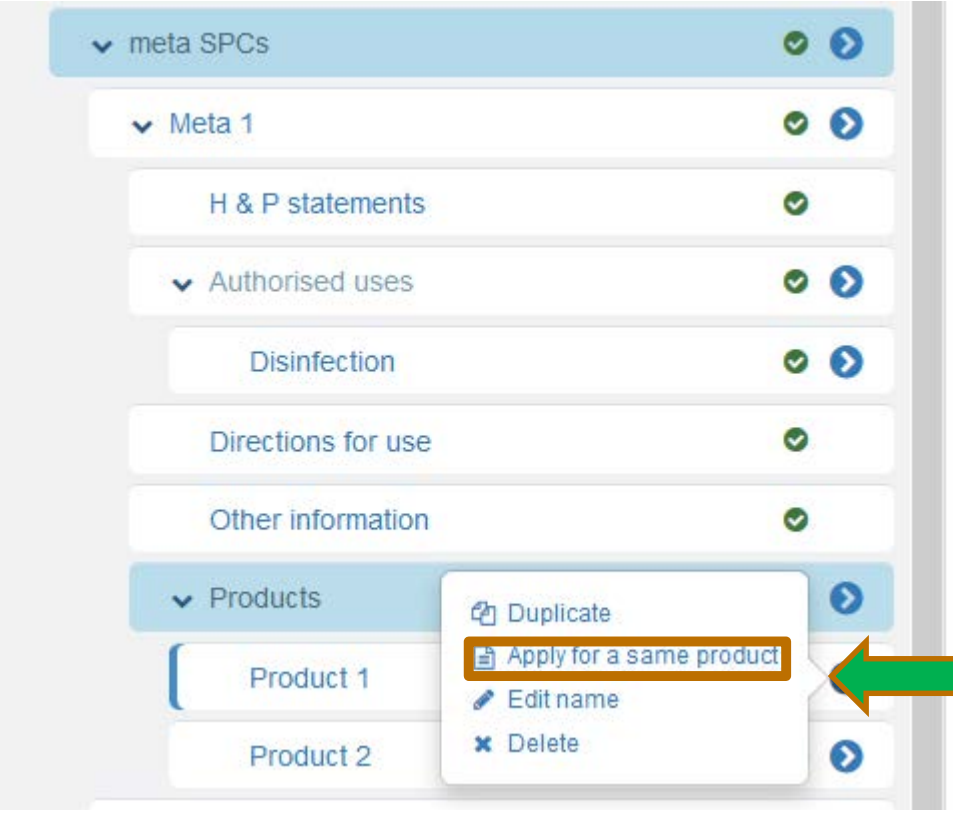
You will have to fill in the following information in the SPC

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

Create a product family SPC for another market area



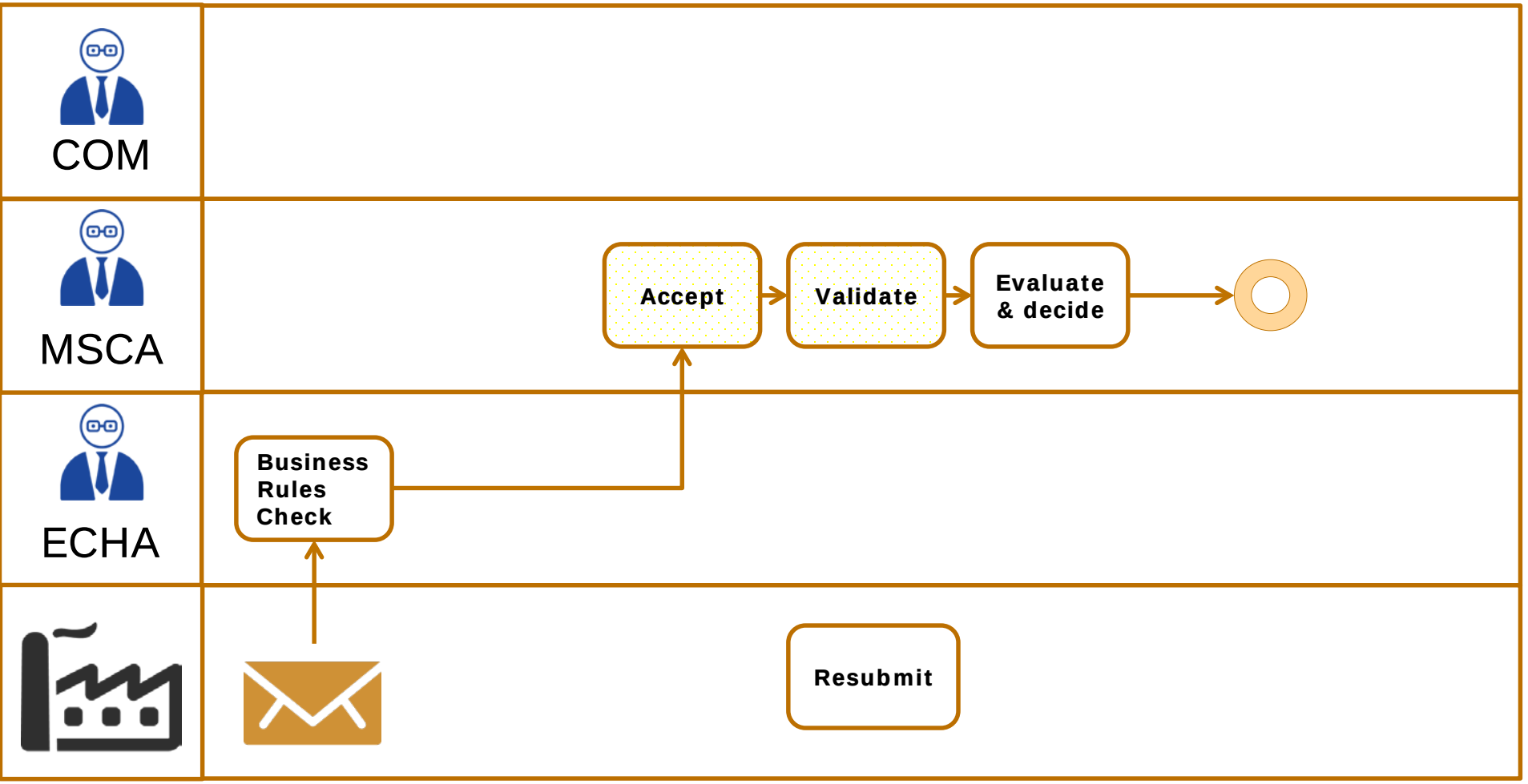
Create a product family SPC for a same biocidal (single) product



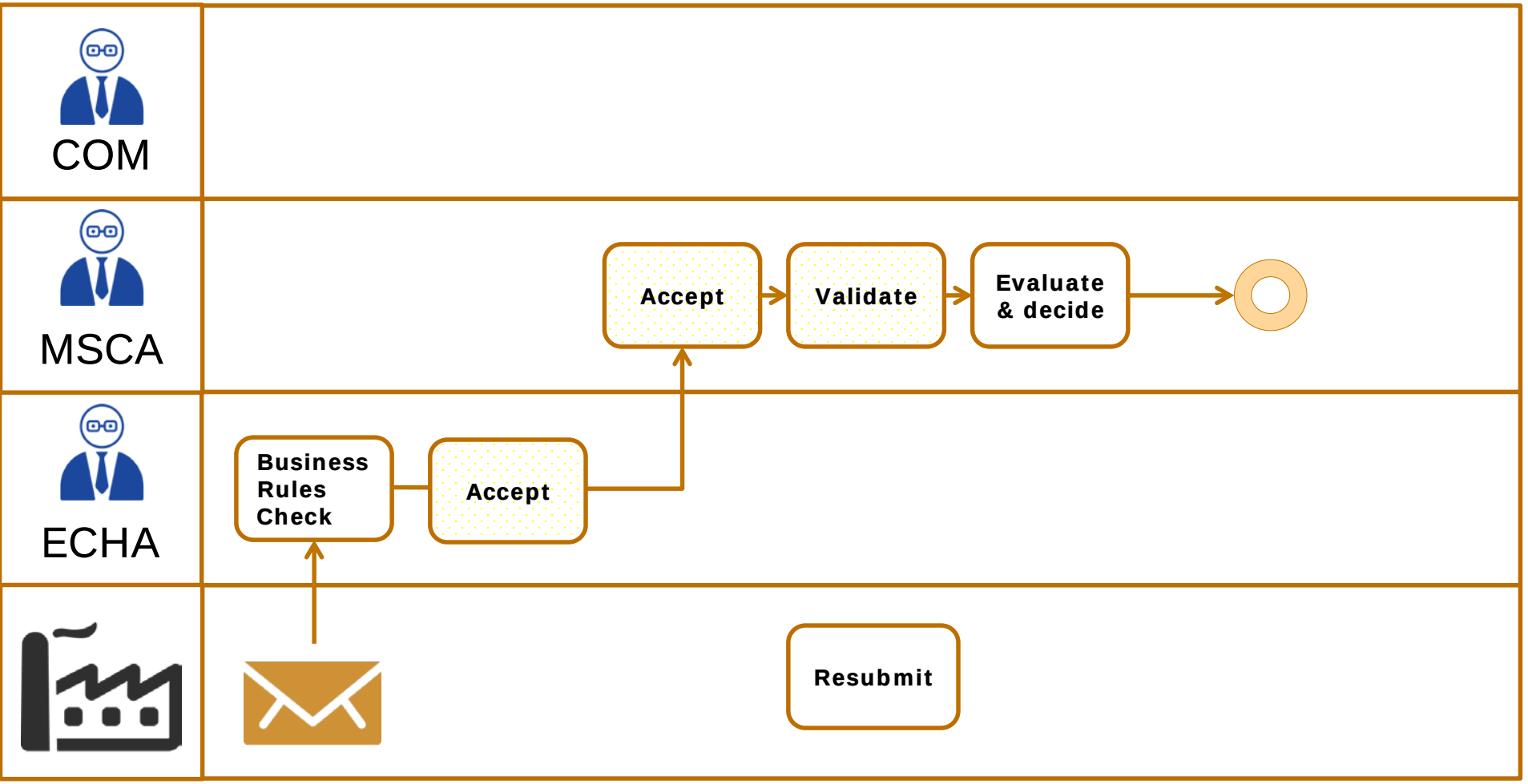
Click here to generate the SPC

Exercise 2 –NA-APP, NA-MRP (65’)

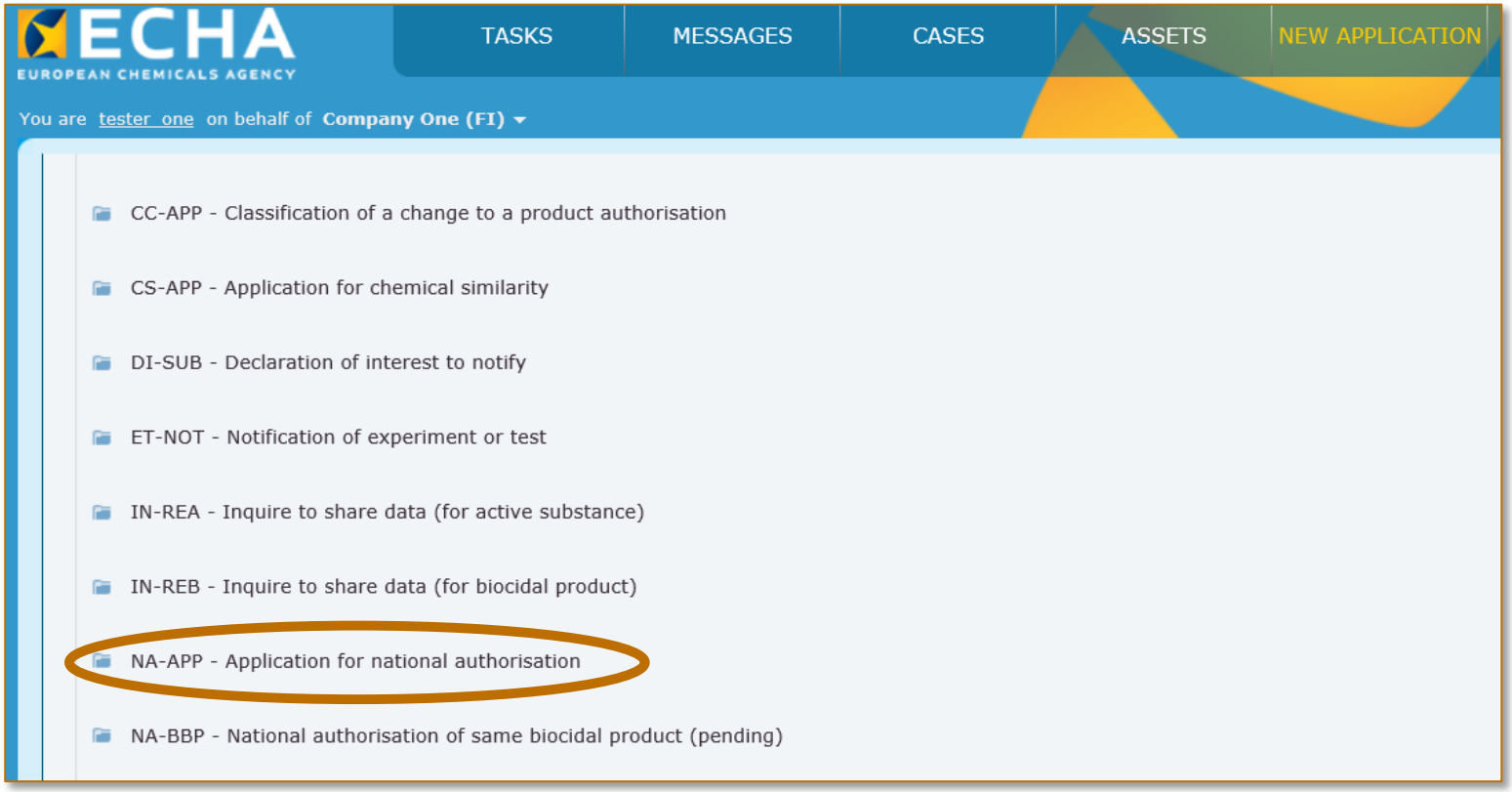
Workflow: National Authorisation (NA-APP)



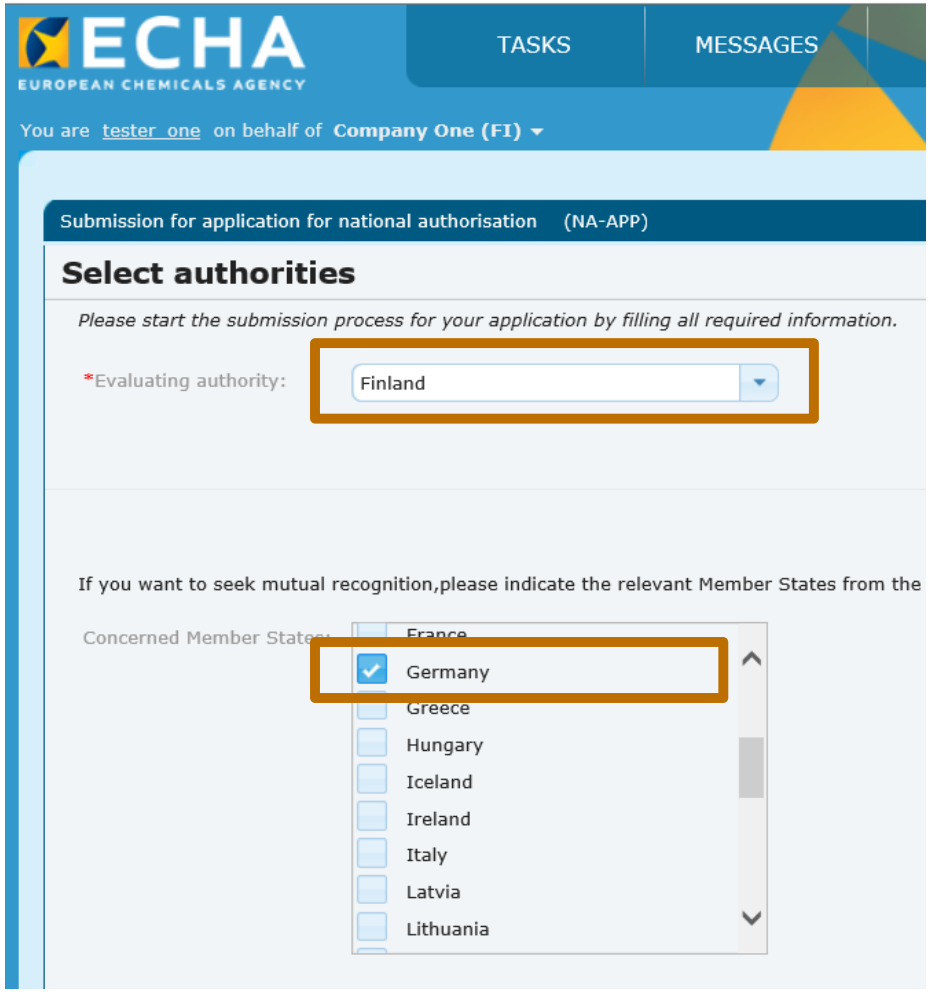
Workflow: Mutual recognition (NA-MRP)



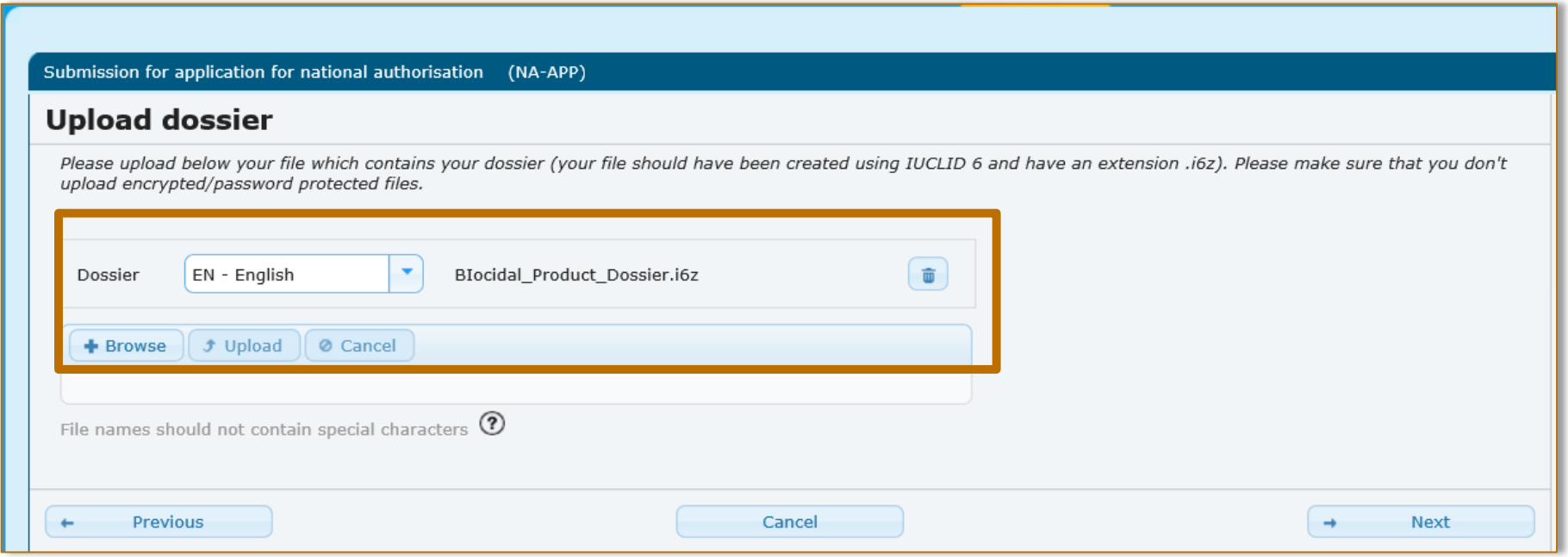
Apply for National Authorisation



Select authorities

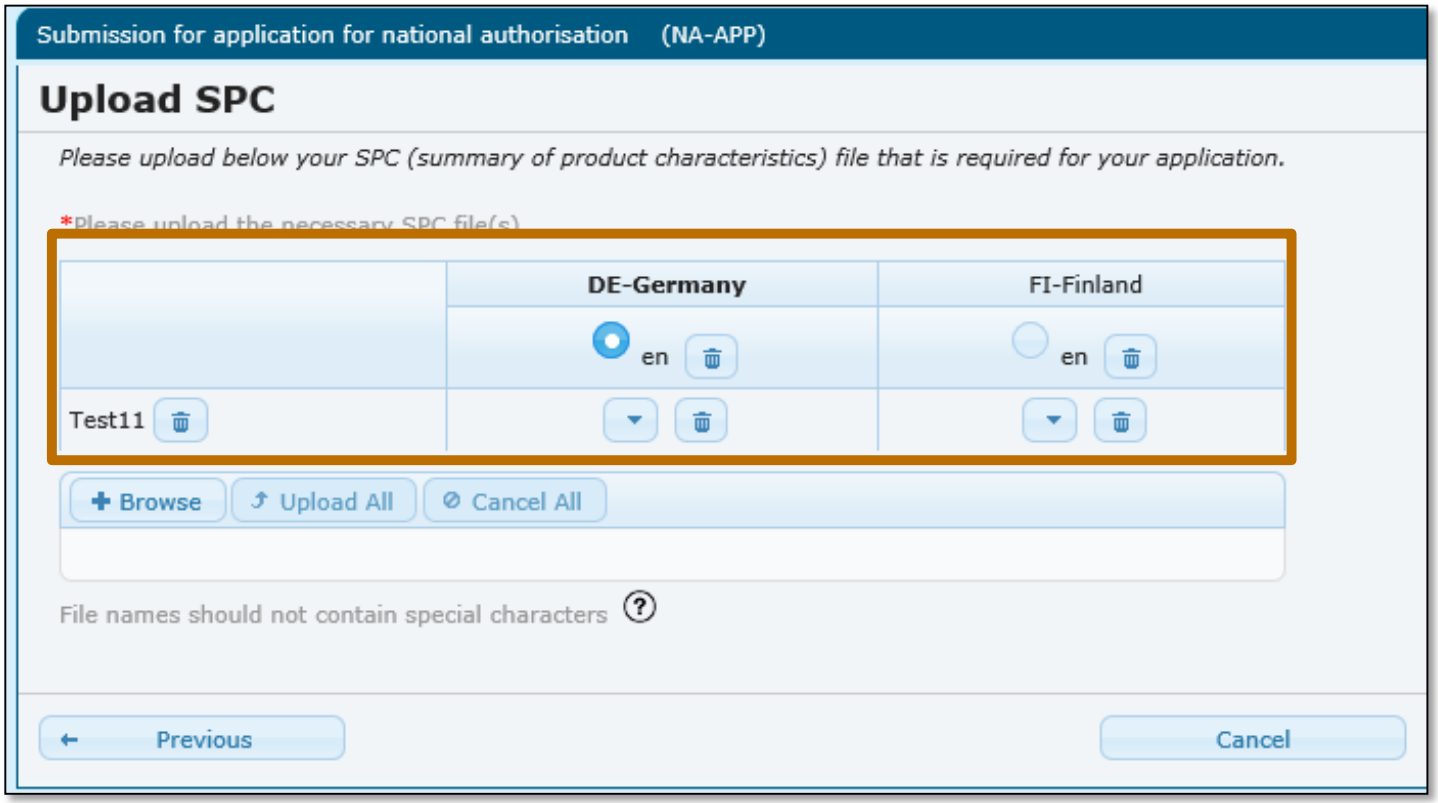


Upload IUCLID 6 dossier

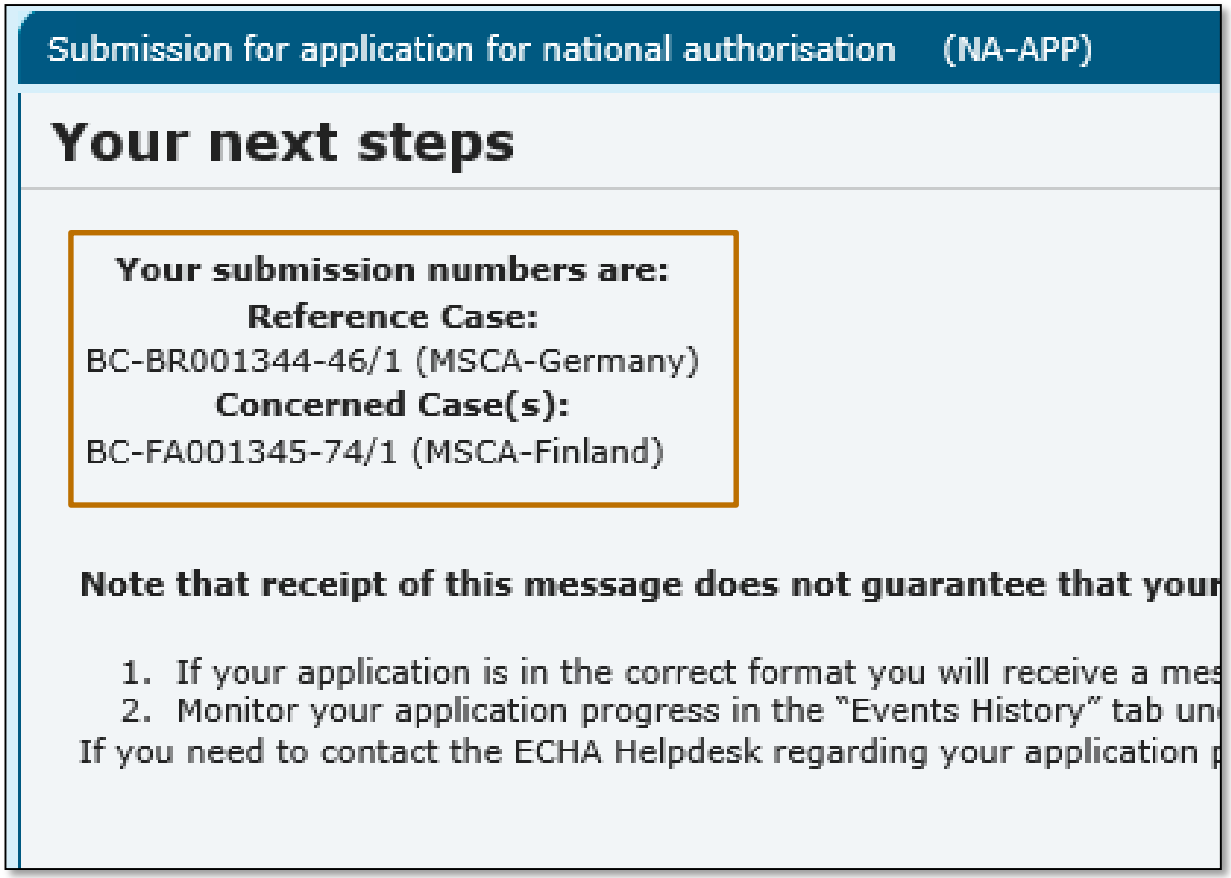


Make sure it is a IUCLID 6 dossier !

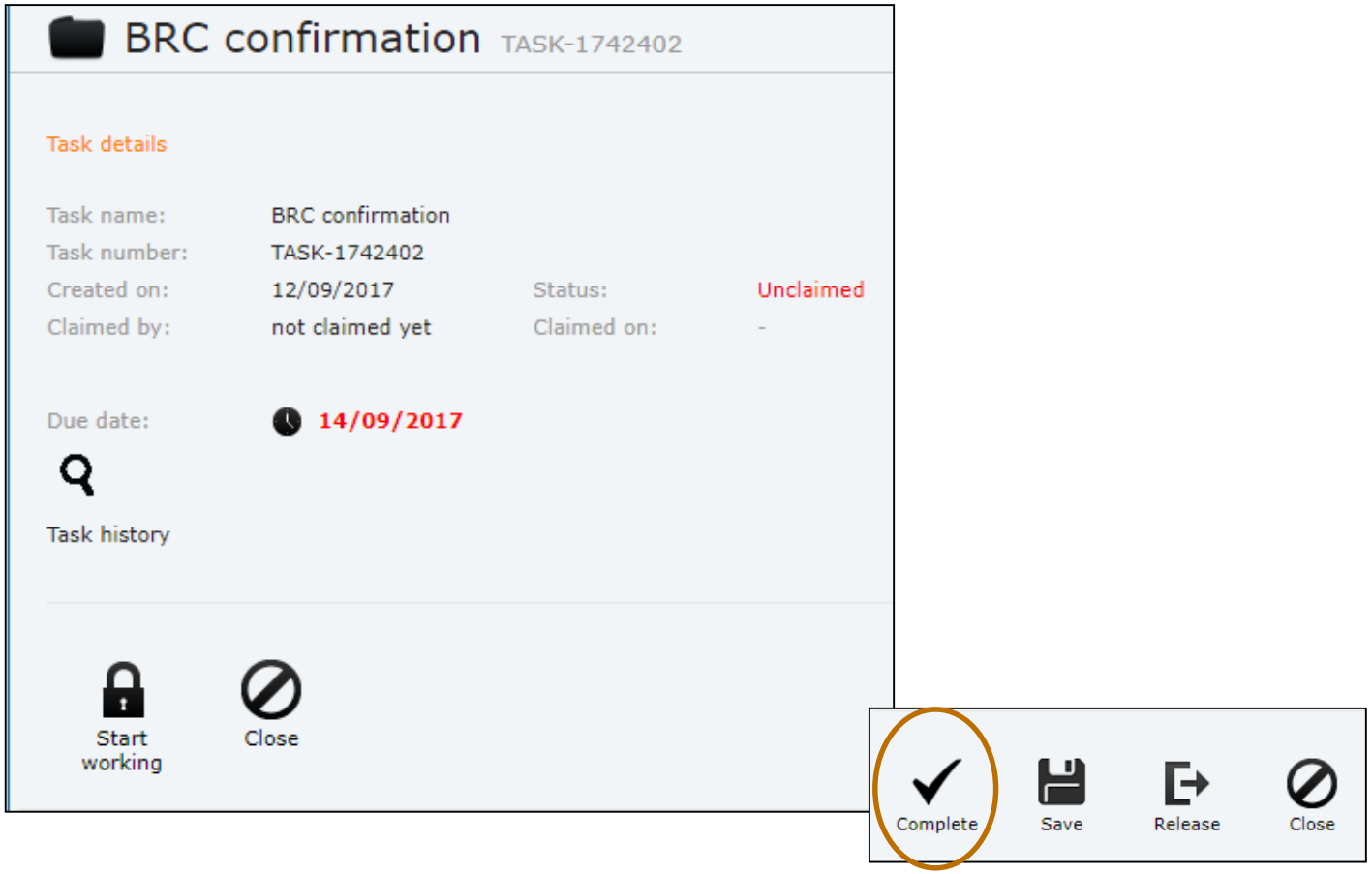
Upload all relevant SPCs



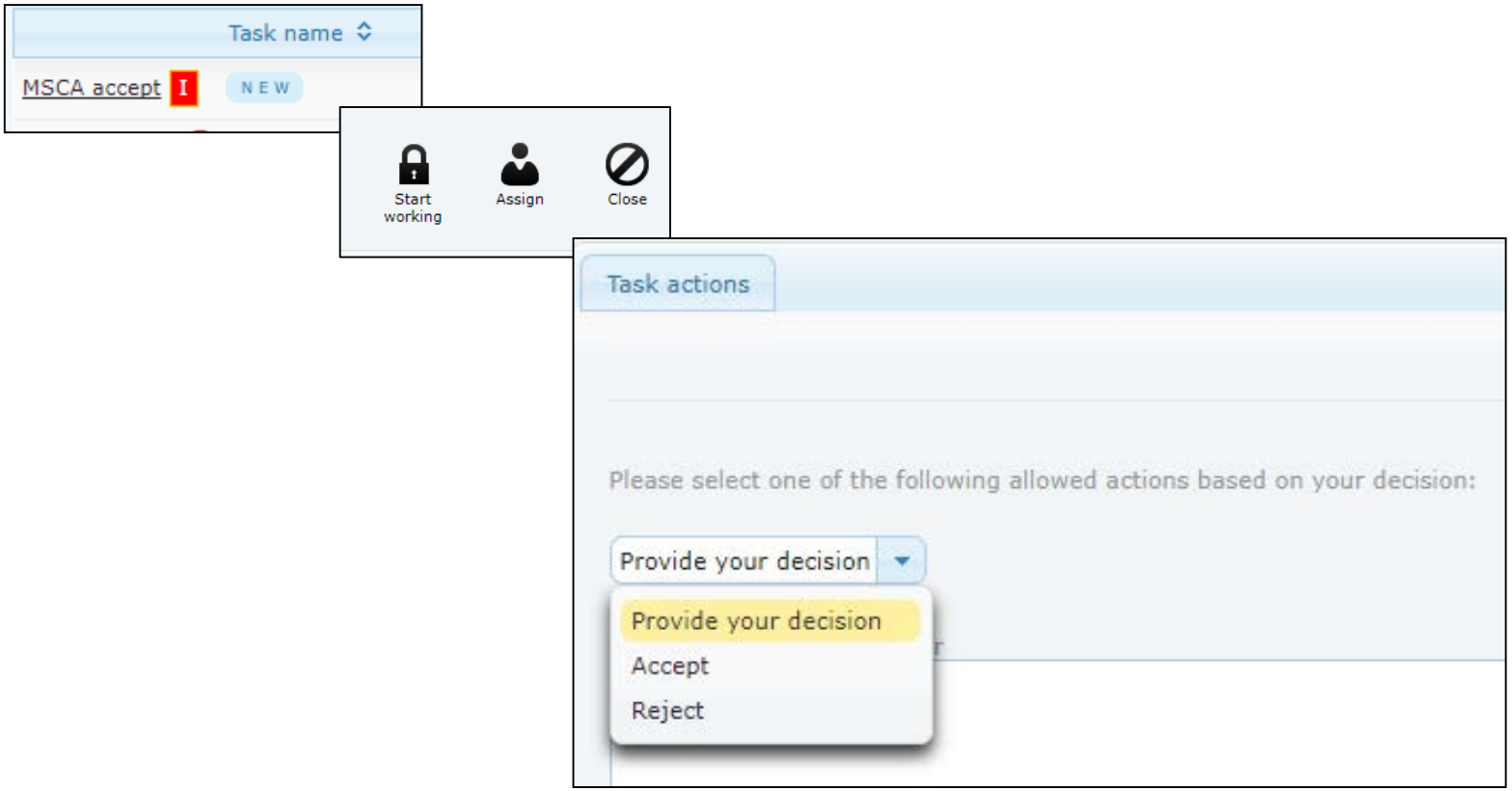
Submit application



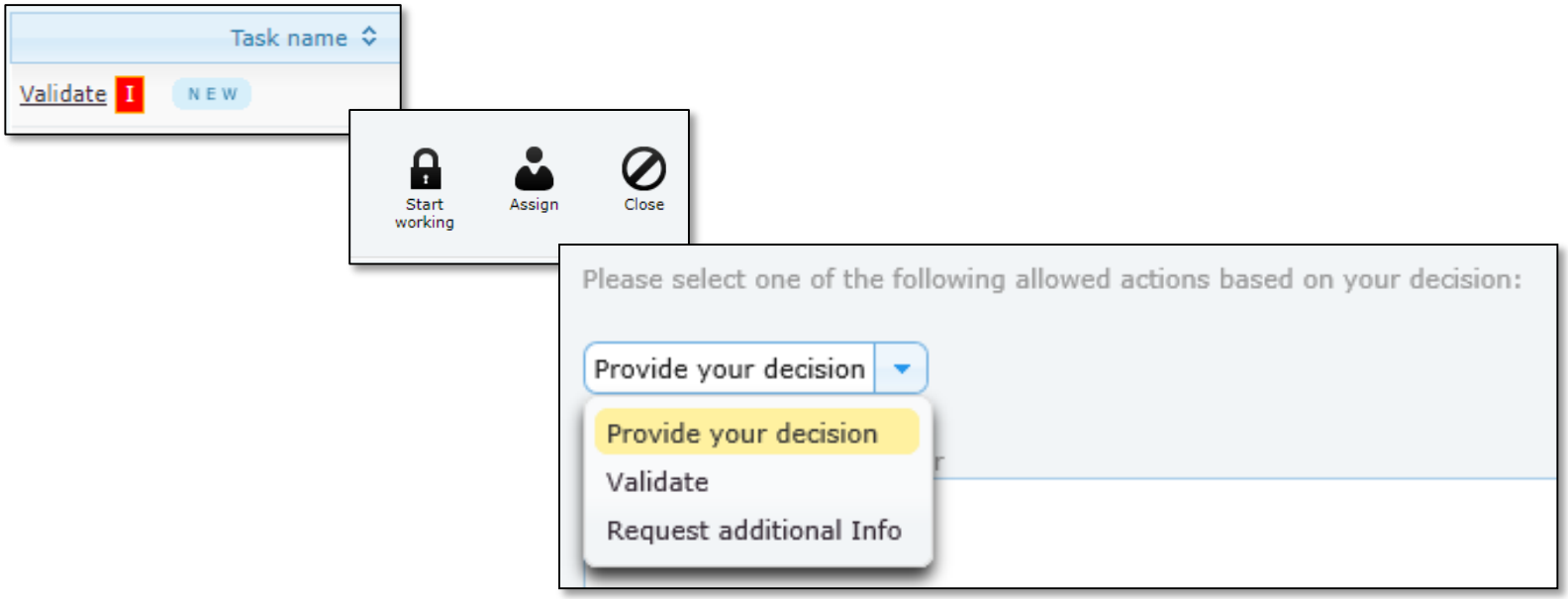
ECHA – Business rules check for case 1 and 2



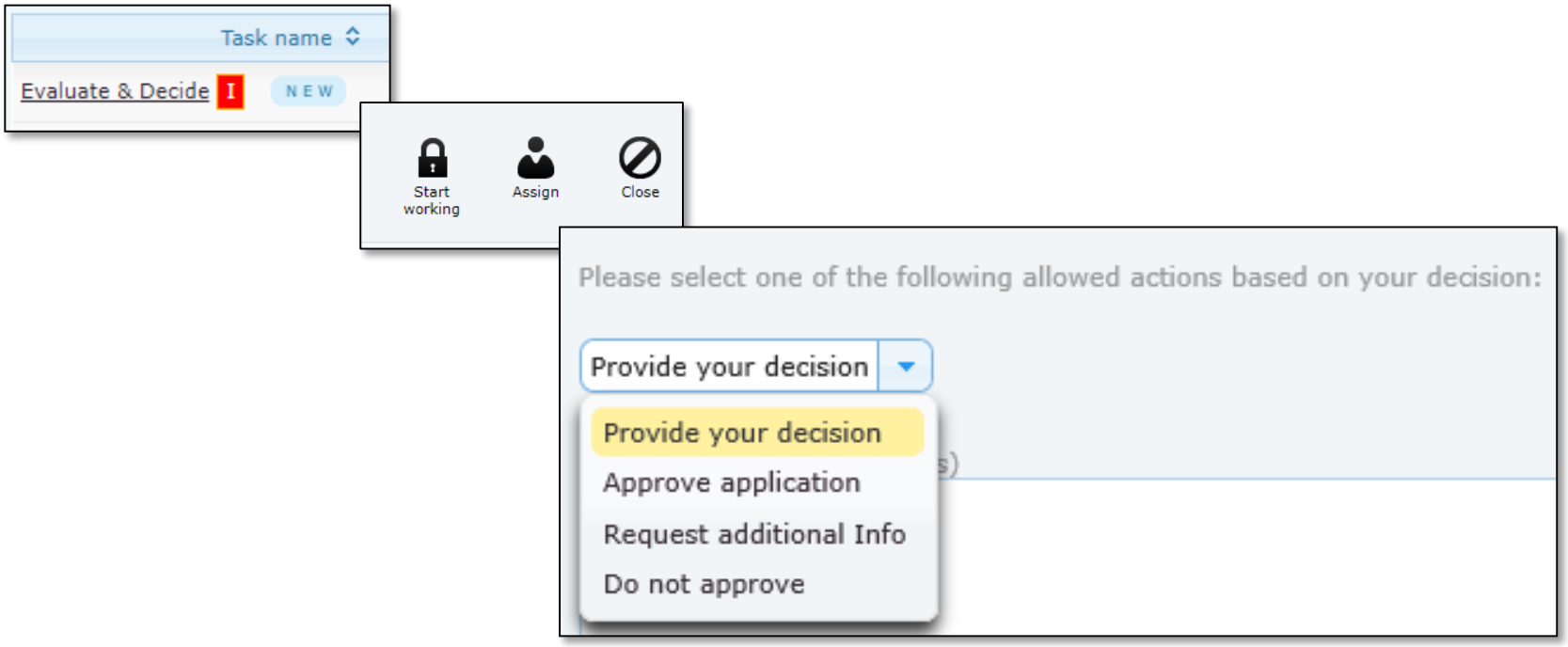
MSCA – Accept for case 1 and 2



MSCA – Validate for case 1 and 2

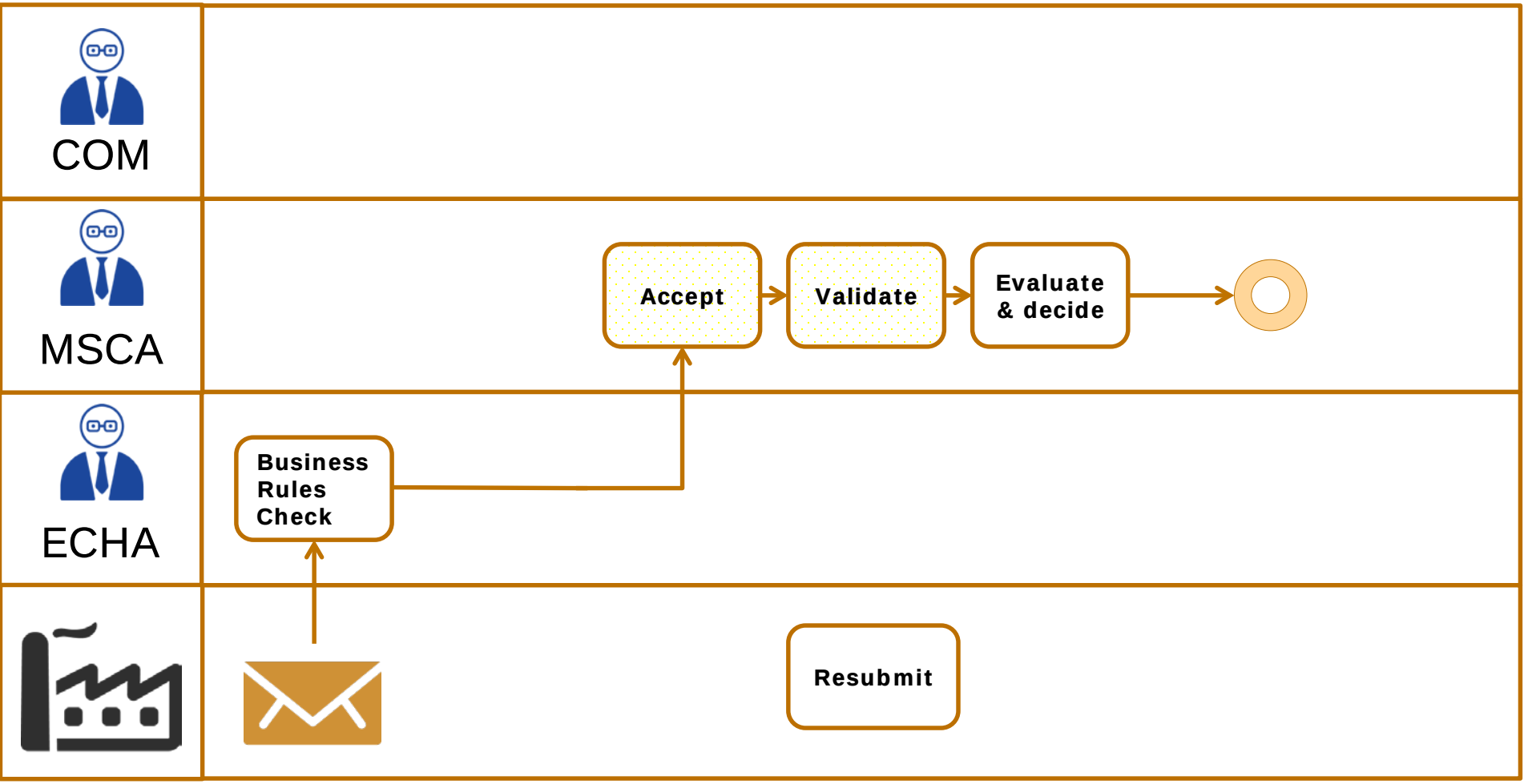


MSCA – Evaluate for case 1 and 2

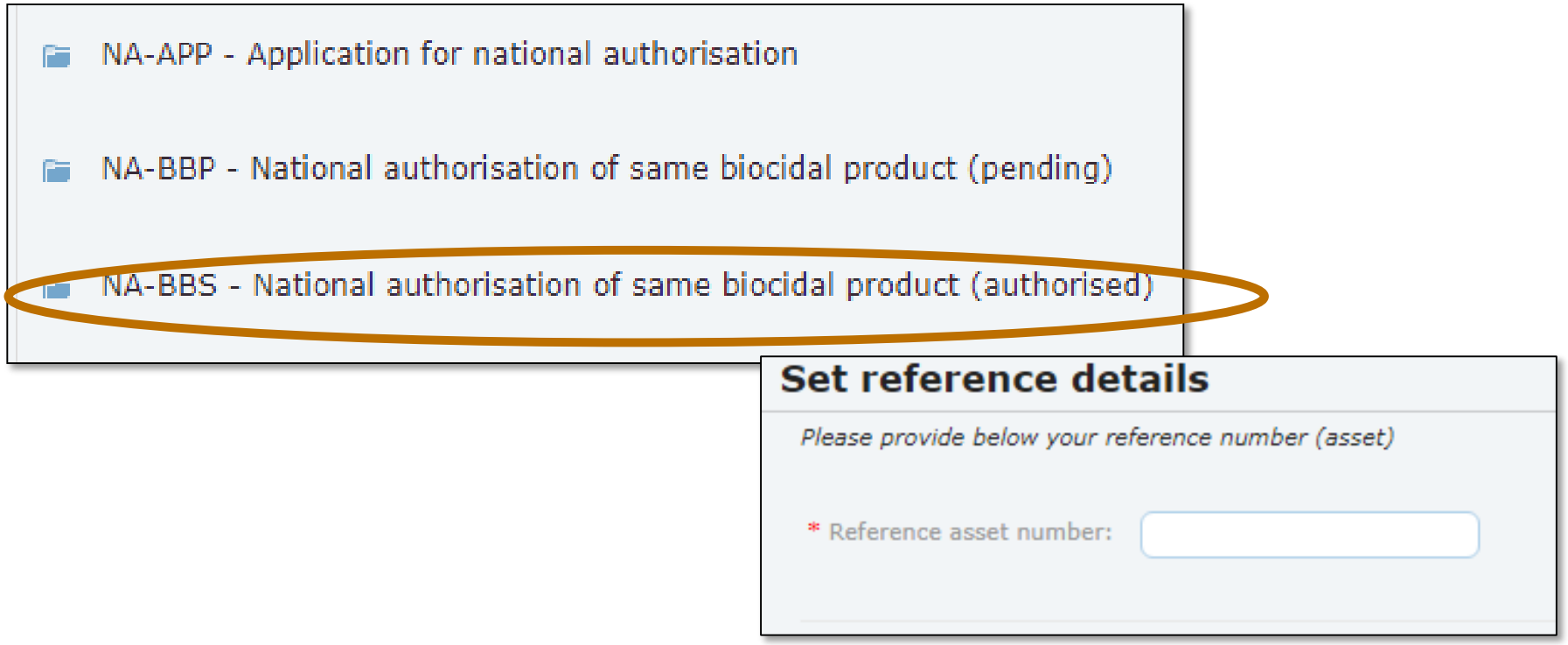


Exercise 3 – Apply for NA-BBS (20’)

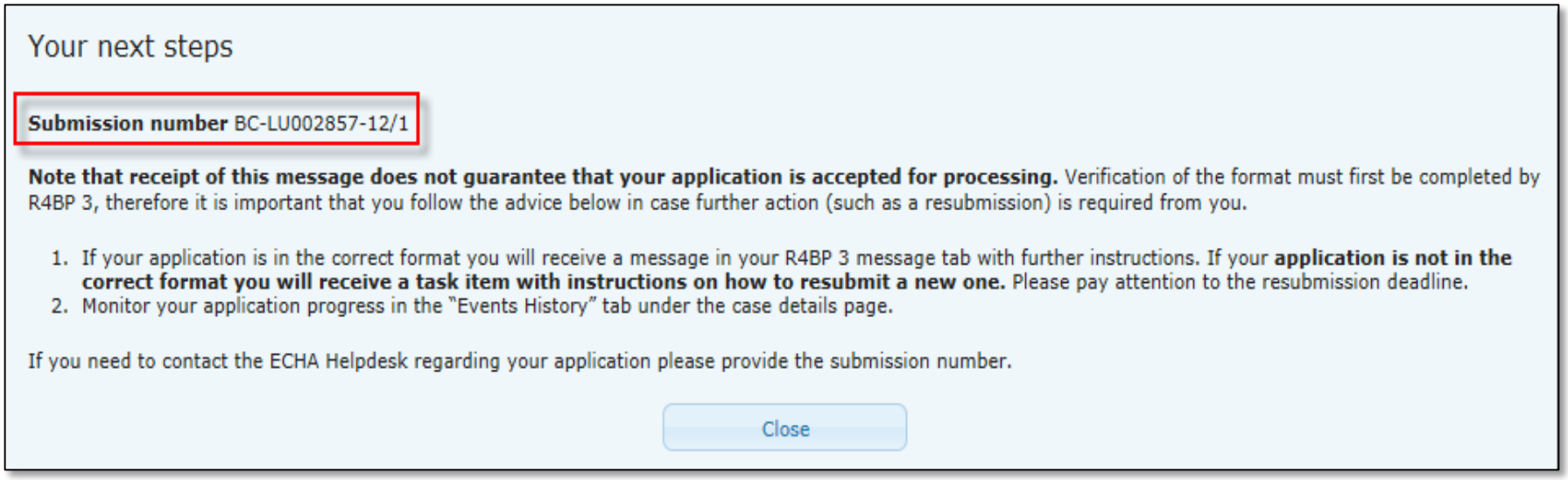
Workflow: National Authorisation of Same Biocidal Product (NA-BBS)



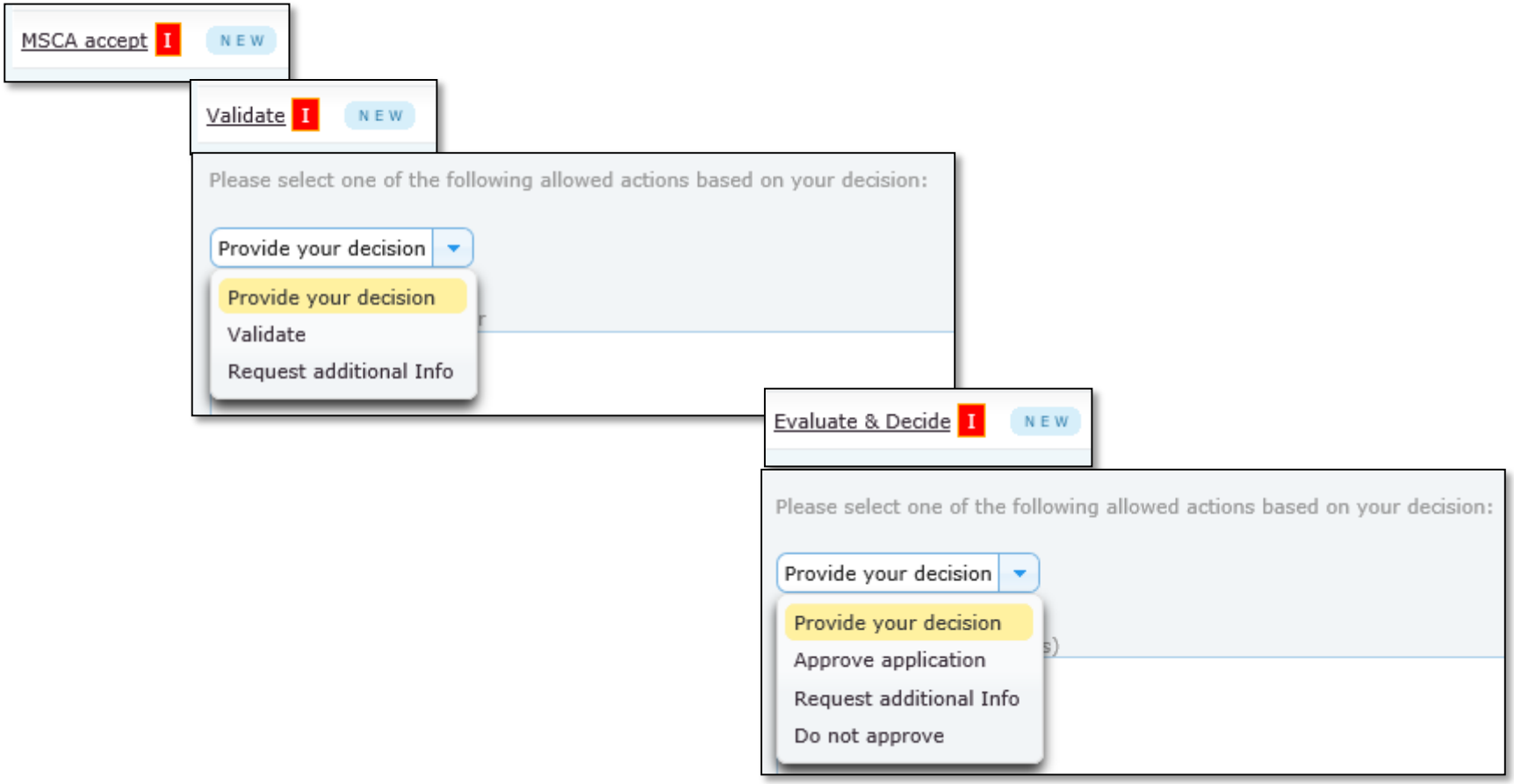
Apply for Same Biocidal Product



Collect the Case number

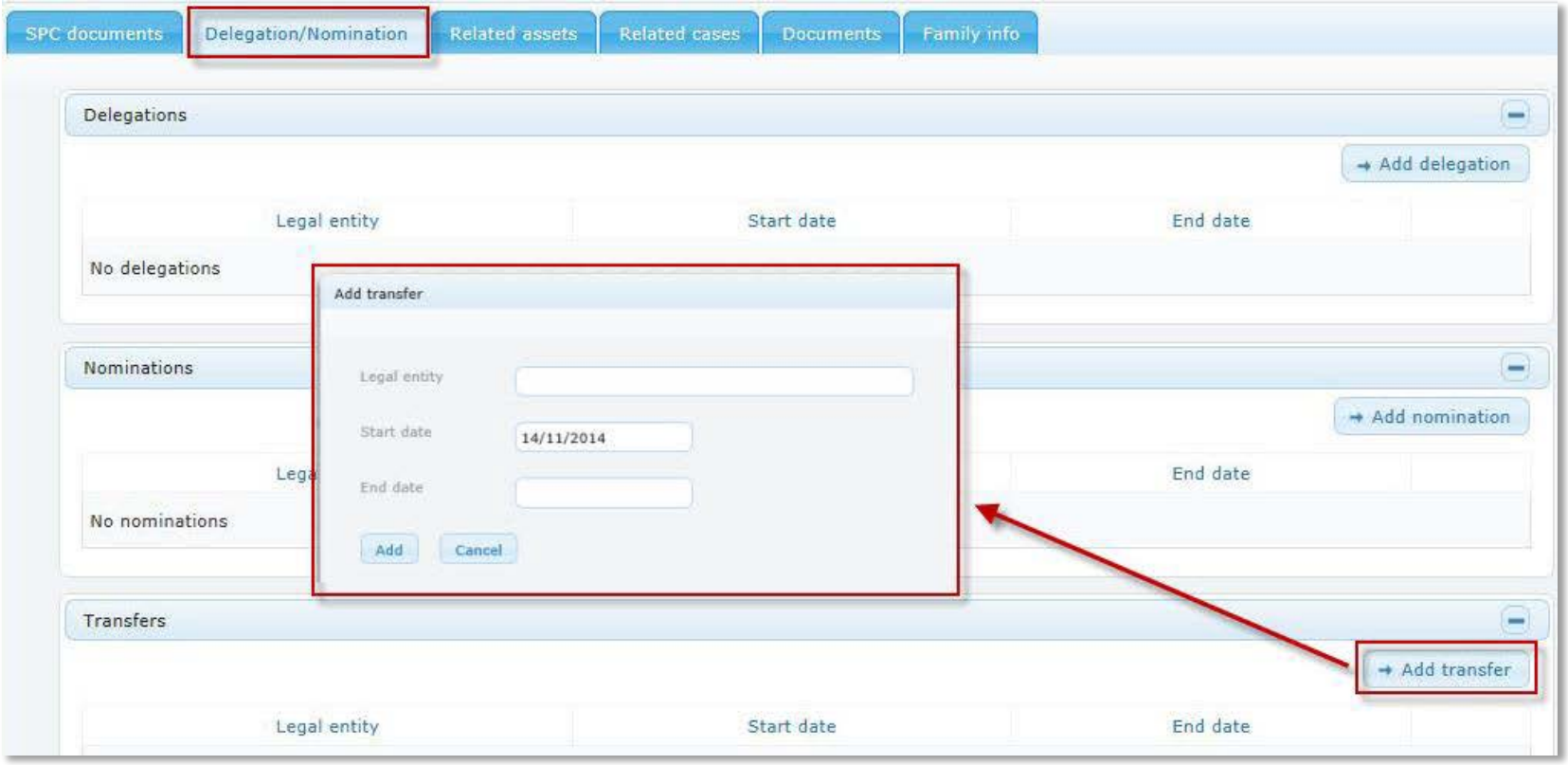
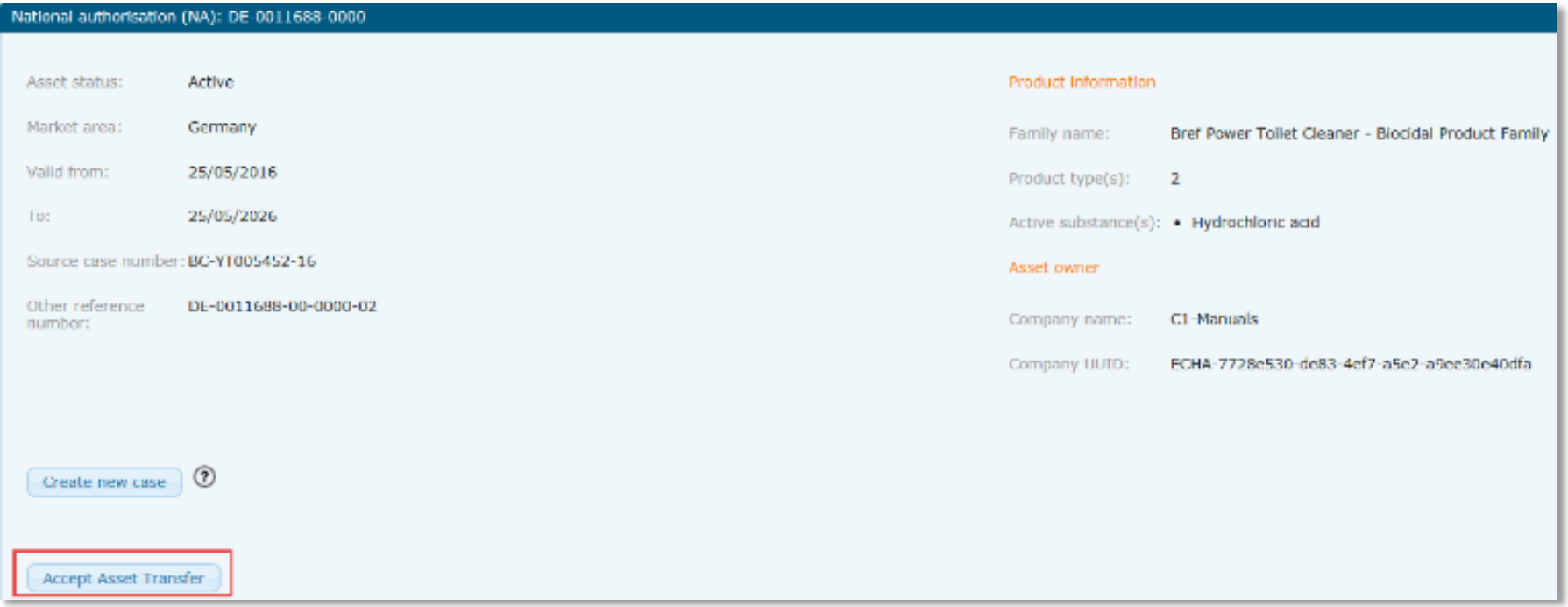


Process the application



Exercise 4 – Transfer an asset (optional)

Add asset transfer



Accept asset transfer