

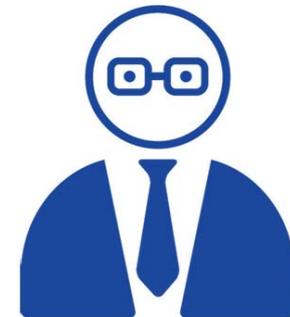
Introduction to R4BP 3 and Summary of Product Characteristics (SPC) editor

Biocides Stakeholders' day IT
training

25 October 2018

Roberto Gilioli
R4BP 3 and SPC editor Product Manager
European Chemicals Agency





Our storyline today

- You are a Regulatory Manager of a chemical company
- Your company produced an “in-situ” generated active substance
- And developed a product with the precursors
- You plan to:
 - Get the “in-situ” active substance approved
 - Market the product in Italy and Finland

You have to deal with Biocides Regulation...

To fulfil your plan you need to:

- Apply to get the approval of your (New) Active Substance (AS)
- Get a NA for the product containing the active substance, in Italy
- Get a NA for the same product in Finland under mutual recognition





How to do that?

BPR requires to submit applications and record authorisations via IT tools:

- ✓ Scientific information on hazards and risks in **IUCLID 6**
- ✓ Administrative information in **SPC** file
- ✓ Submissions, communications and recording of the evaluations by Competent Authorities in **R4BP 3**

Today we will...

- Quickly introduce R4BP 3 and SPC editor
- Show you how to use them to fulfil your plan by:
 - ✓ Guiding you in targeted exercises to perform the required applications in R4BP 3 and prepare SPCs, when needed
 - ✓ Demonstrating how Competent Authorities are recording their evaluations
 - ✓ Giving you the chance to try yourself the features

SPC editor basics



Summary of Product Characteristics

- Standard, electronic and non-confidential component of a product 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

Product name: Disinfect Now

Product type(s): PT05 - Drinking water (Disinfectants)

Authorisation number:

R4BP 3 asset reference number:

AFT

How to prepare it?

- To be filled in electronic format
- The information requirements are different for:

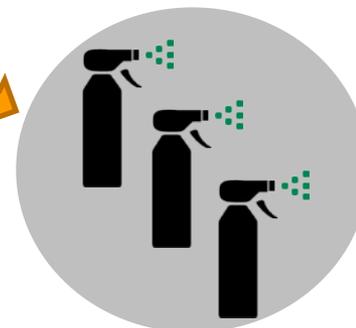
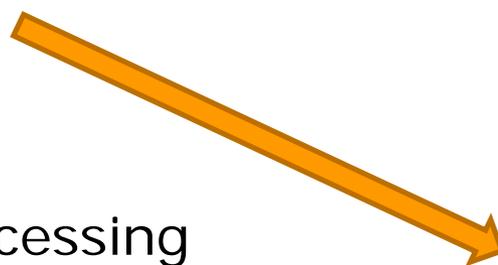
- ✓ Single products
- ✓ Product families



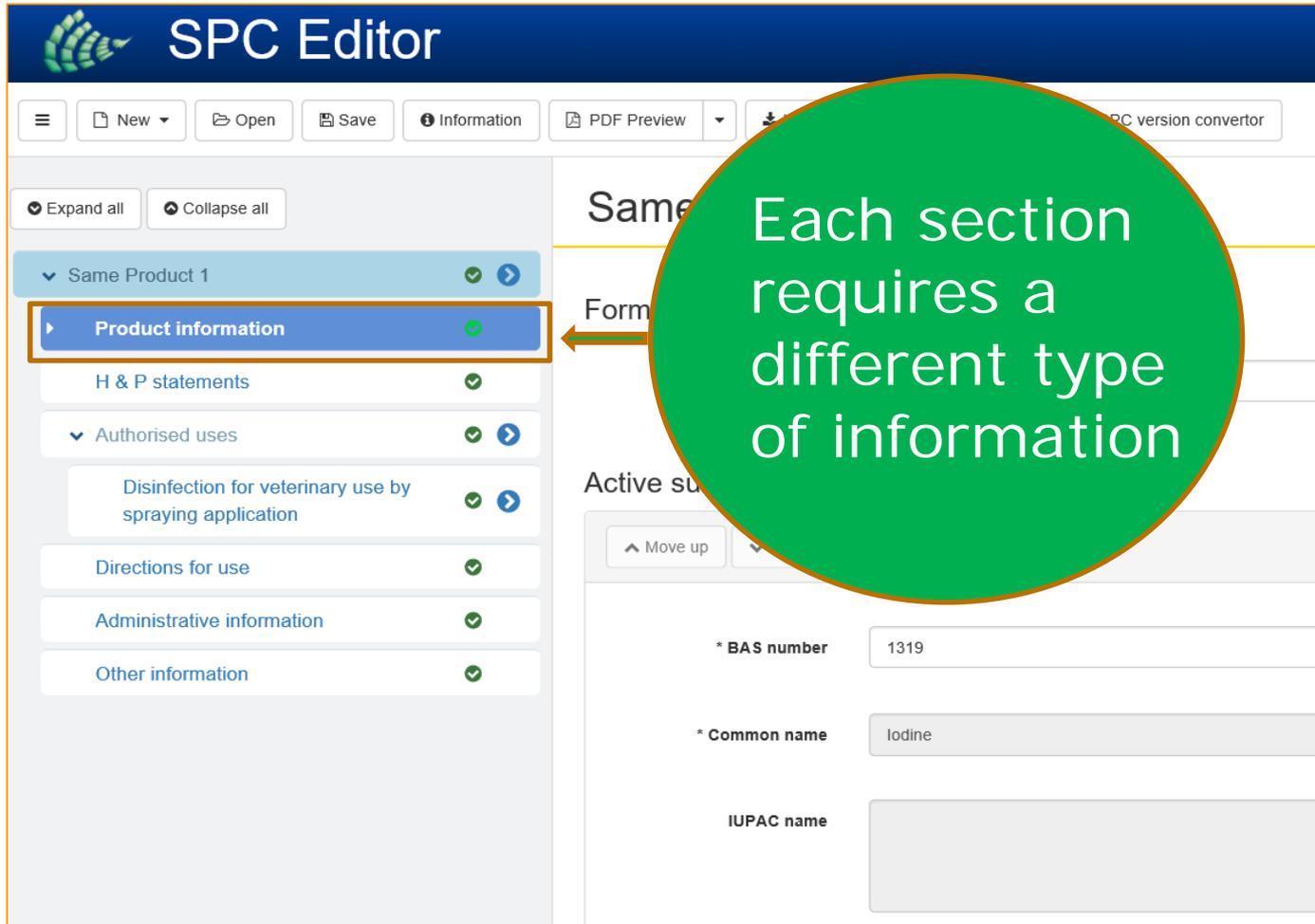
SPC editor

- Used for:

- ✓ R4BP 3 data processing
- ✓ Dissemination
- ✓ Comparison



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

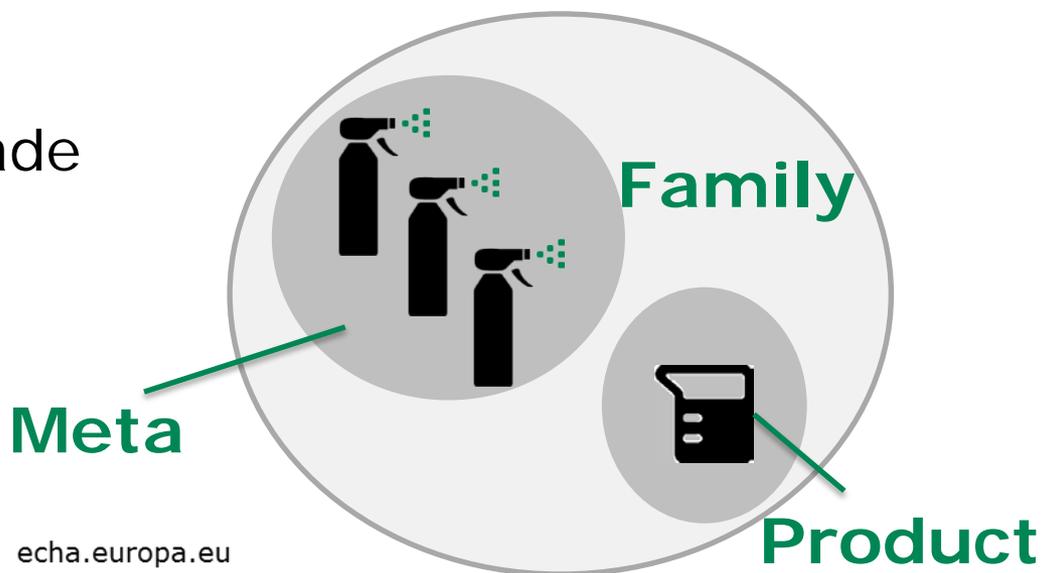
IUPAC name

Each section requires a different type of information

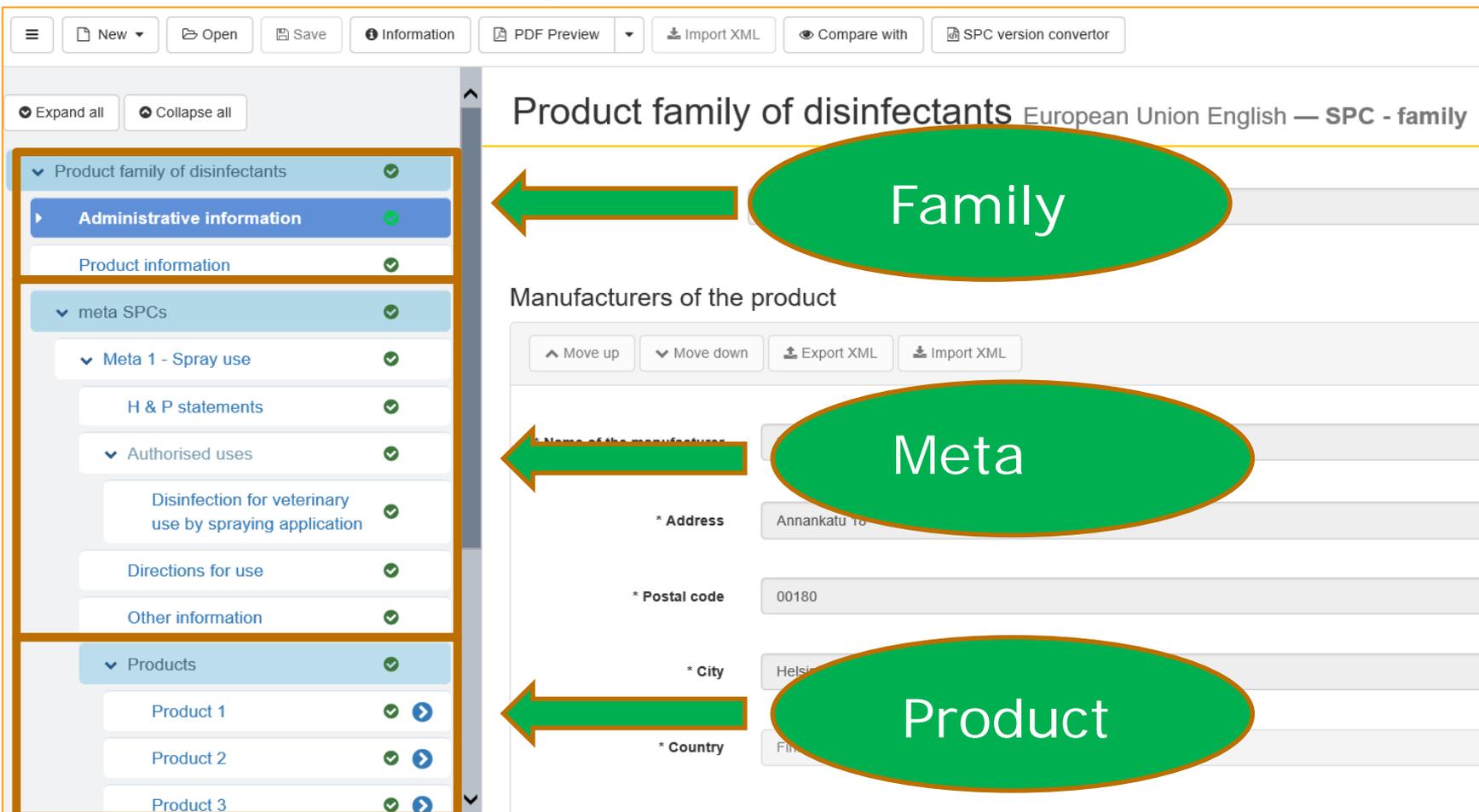
Product Family SPC

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



Product family of disinfectants European Union English — SPC - family

Administrative information

Product information

meta SPCs

Meta 1 - Spray use

H & P statements

Authorised uses

Disinfection for veterinary use by spraying application

Directions for use

Other information

Products

Product 1

Product 2

Product 3

Manufacturers of the product

Move up Move down Export XML Import XML

Name of the manufacturer

* Address Annankatu 10

* Postal code 00180

* City Helsinki

* Country Finland

Family

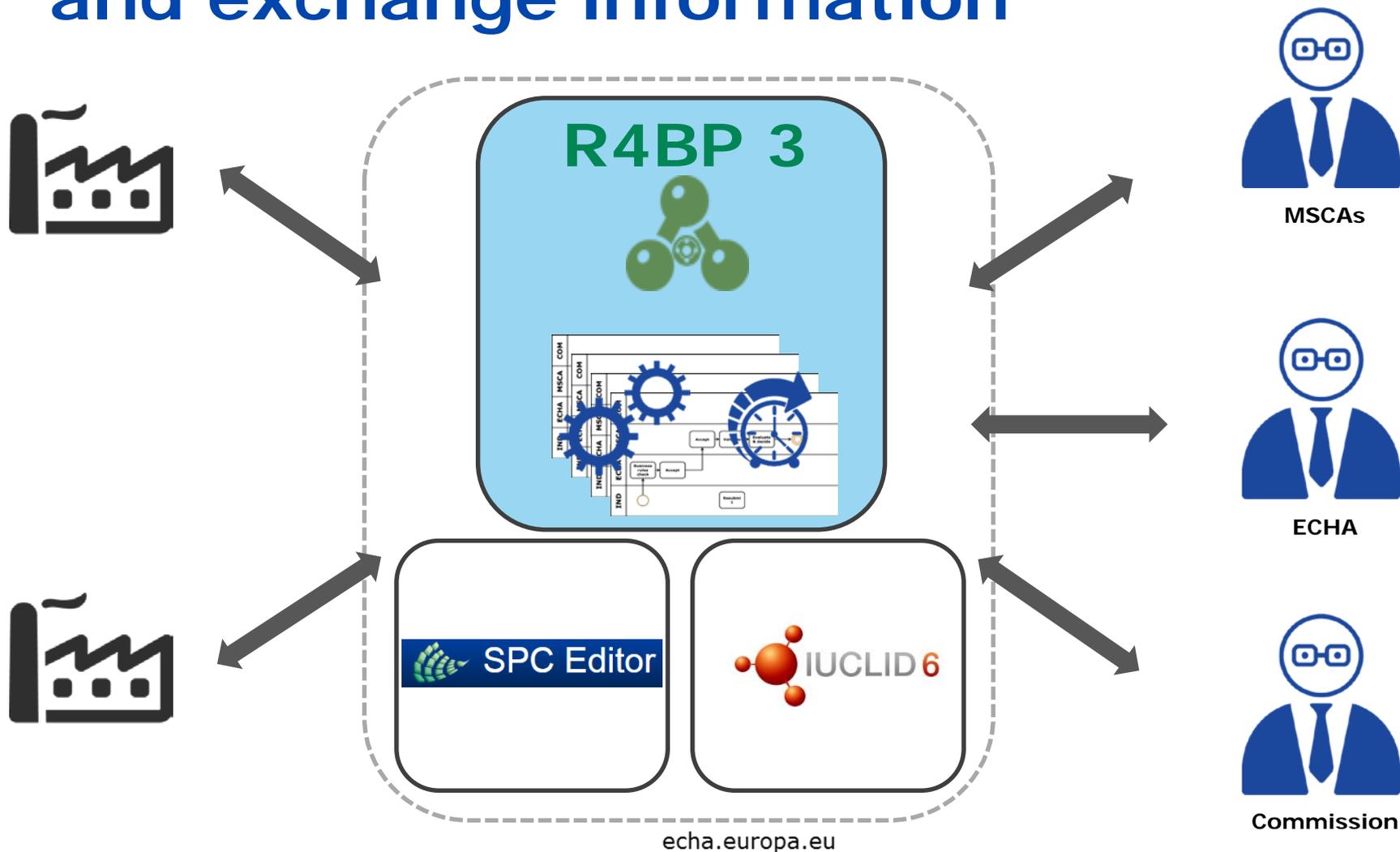
Meta

Product

R4BP 3 basics



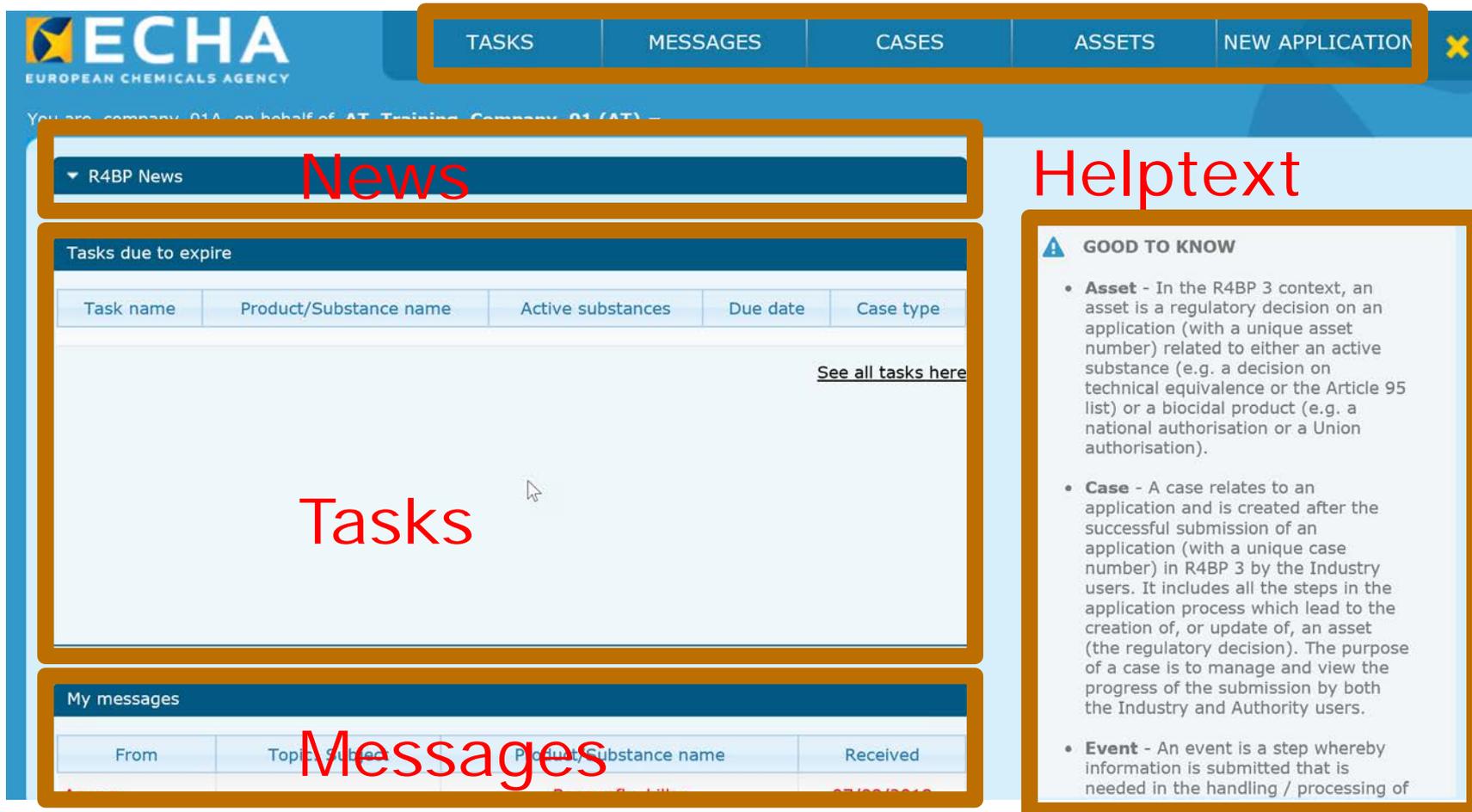
Central hub to comply with legislation and exchange information



Level playing field for EU companies and authorities

- Information on applications in a unique and secure place, retrievable and viewable
- Wizards to help applicants
- Tasks and deadlines for authorities
- Exports of the information can be generated

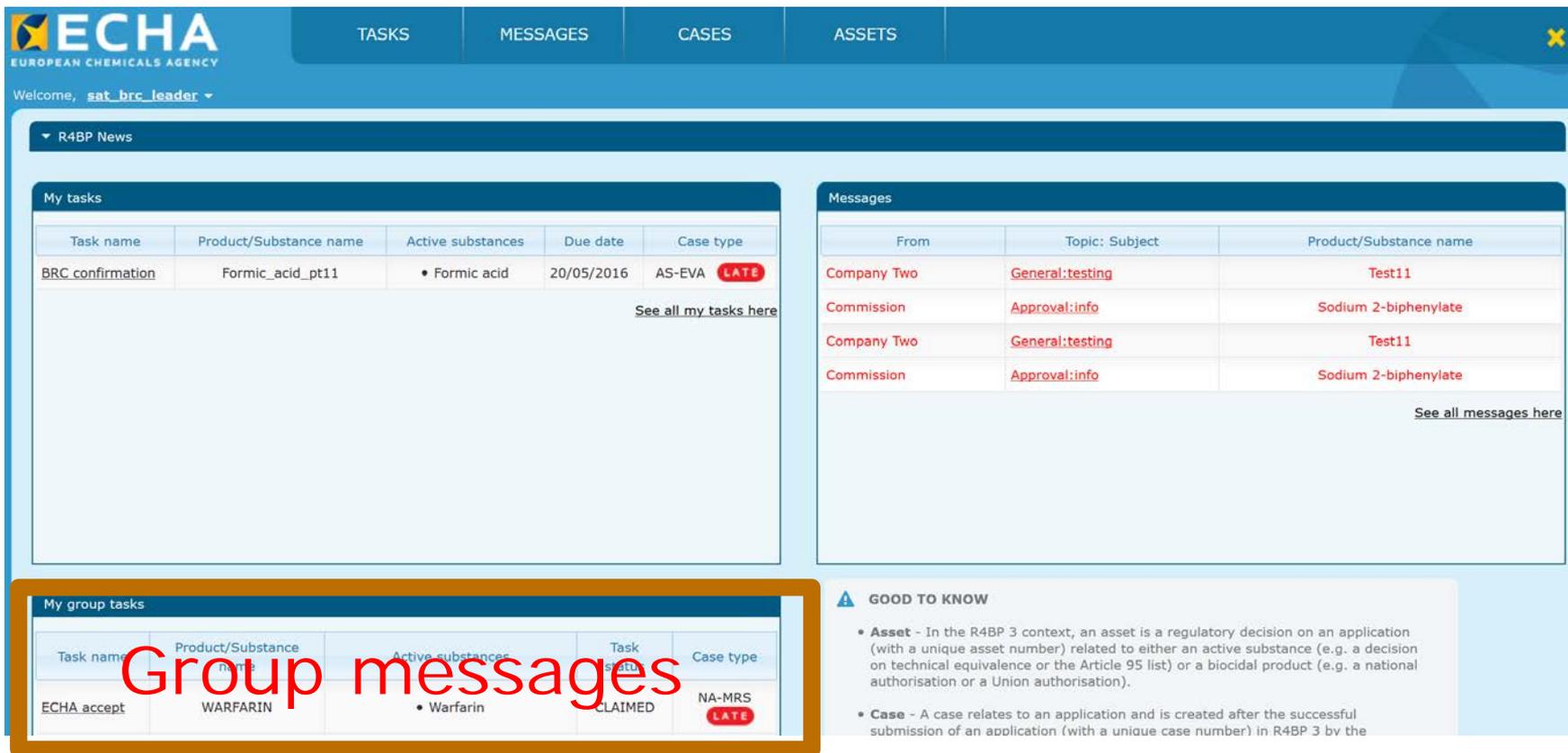
R4BP 3 User Interface (IND) Task bar



The screenshot displays the R4BP 3 User Interface (IND) with several key sections highlighted:

- Task bar:** A horizontal navigation bar at the top containing buttons for TASKS, MESSAGES, CASES, ASSETS, and NEW APPLICATION.
- News:** A section titled "R4BP News" with a red "News" label overlaid.
- Tasks:** A section titled "Tasks due to expire" containing a table with columns: Task name, Product/Substance name, Active substances, Due date, and Case type. A red "Tasks" label is overlaid on this section.
- Messages:** A section titled "My messages" containing a table with columns: From, Topic, Subject, Product/Substance name, and Received. A red "Messages" label is overlaid on this section.
- Helptext:** A section titled "GOOD TO KNOW" providing definitions for Asset, Case, and Event. A red "Helptext" label is overlaid on this section.

R4BP 3 User Interface (AUTH)



The screenshot displays the R4BP 3 User Interface (AUTH) with the following components:

- Navigation Tabs:** TASKS, MESSAGES, CASES, ASSETS
- User Profile:** Welcome, [sat_brc_leader](#)
- R4BP News:** A dropdown menu for news items.
- My tasks:** A table listing tasks for the user.

Task name	Product/Substance name	Active substances	Due date	Case type
BRC confirmation	Formic_acid_pt11	• Formic acid	20/05/2016	AS-EVA LATE

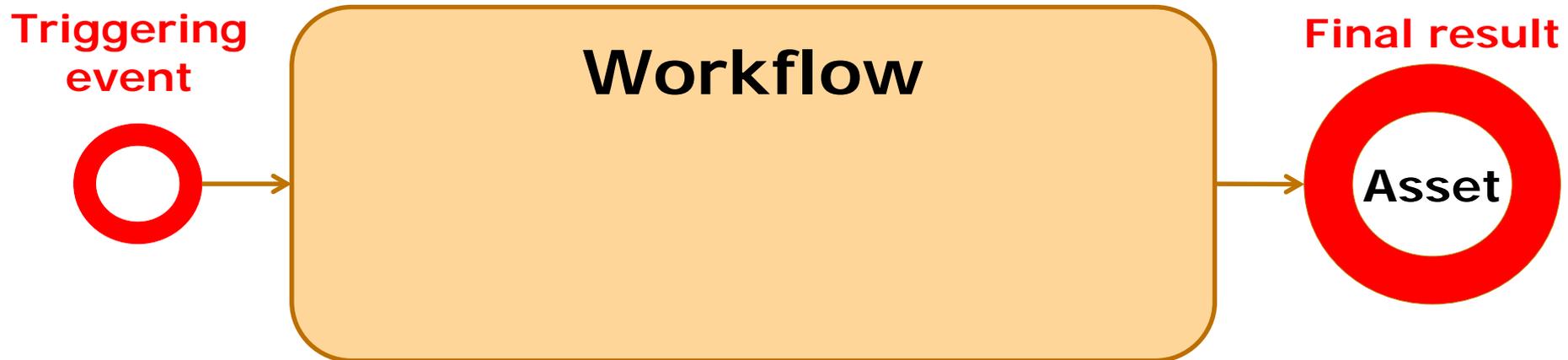
[See all my tasks here](#)
- Messages:** A table listing messages.

From	Topic: Subject	Product/Substance name
Company Two	General:testing	Test11
Commission	Approval:info	Sodium 2-biphenylate
Company Two	General:testing	Test11
Commission	Approval:info	Sodium 2-biphenylate

[See all messages here](#)
- My group tasks:** A table listing tasks for the group.

Task name	Product/Substance name	Active substances	Task status	Case type
ECHA_accept	WARFARIN	• Warfarin	CLAIMED	NA-MRS LATE
- 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

BPR processes as IT workflows



BPR processes implemented

- Almost all:
 - ✓ 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

Triggering event: new Application

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

Submit application for:

-  Active substance 
-  National authorisation 
-  Simplified authorisation 
-  Union authorisation 
-  Other 

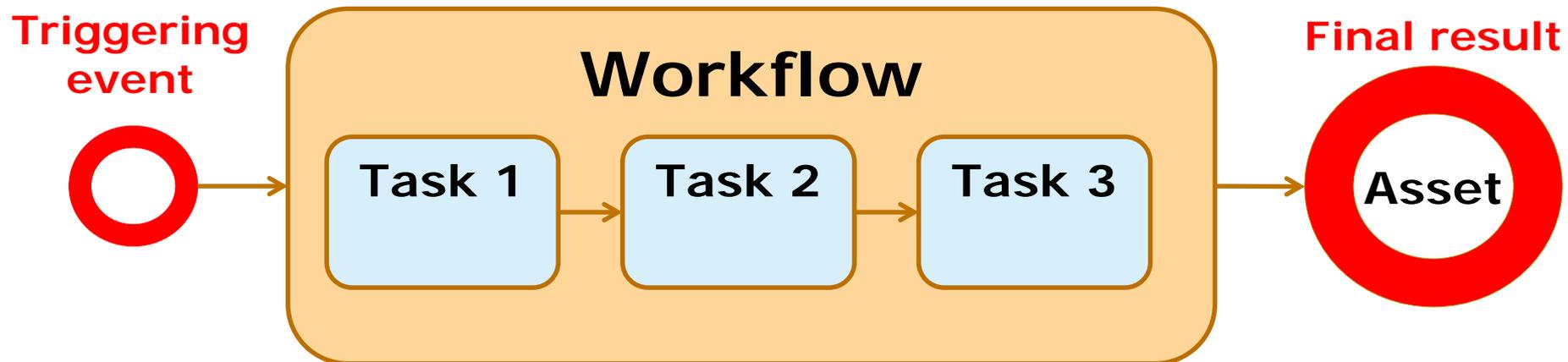
Assets



- Positive outcome on an application
- Unique asset number

Assets list							
Asset number ⌵	Product/Substance name ⌵	Active substances	Product type (s)	Asset type ⌵	Expiration date ▼	Start renewal by ⌵	Asset status ⌵
<u>IT-0001061-0000</u>	Insecticide Product	• margosa extract	• PT18	NA	09/08/2028	06/02/2027	Active
<u>IT-0001041-0000</u>	Disinfectant product	• Hydrogen peroxide	• PT02	NA	07/08/2028	04/02/2027	Active
<u>IT-0000981-0000</u>	Disinfectant Product	• Hydrogen peroxide	• PT02	NA	02/05/2028	30/10/2026	Active

Process steps as workflow tasks



Tasks – You are required to act



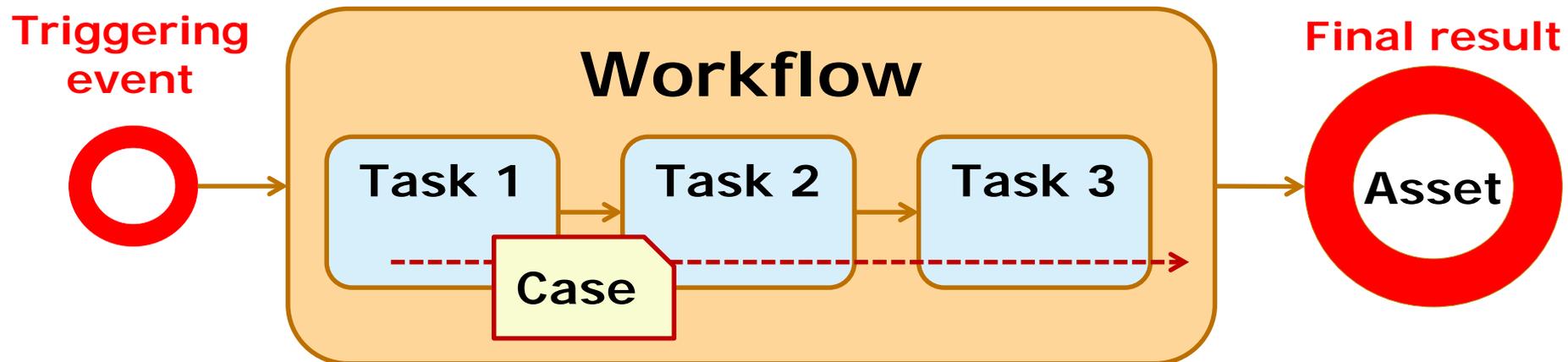
- E.g. Resubmission & Reply (*Process, for Authorities*)
- Due date!
- Email alerts to applicant
- Search / filter / export

Search Clear Export (.xls)

Tasks list

Task name ⇅	Case number ⇅
Reply to communication 	BC-TK012895-22

Sequence of tasks = Case



Cases – Your submissions



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

- The events history displays Communication and System events, occurred from initial submission to final decision for a case.
- Default sorting is by event date (newest on top)

Date ↕	Step	Subject	Sender
14/08/2018 14:05:55	MSCA Acceptance	MSCA acceptance started, due by 13/09/2018	
14/08/2018 14:05:54	ECHA Acceptance	Submission accepted by ECHA [NMS-C-1004389-04-00/F]	Agency
14/08/2018 14:00:01	Invoicing	Invoices or credit notes sent [NMS-C-1004407-21-00/F]	Agency
14/08/2018 13:57:23	Submission	ECHA acceptance started, due by 18/09/2018	
14/08/2018 13:57:15	Format Checks	Submission format verified [NMS-C-1004388-05-00/F]	Agency
14/08/2018 13:27:13	Format Checks	BRC confirmation started, due by 16/08/2018	
14/08/2018 13:27:00	Submission	Initial submission [BC-JM002083-51/1]	AT_Training_Company_01

Messages



- Sent, Received, Archived, in cc...
- Permanent records, unique identifiers
- Notification of new messages

Message list

Archive

<input type="checkbox"/>		Sender	Topic: Subject	Case number	Product/Substance name	Received Date
<input type="checkbox"/>		Agency	<u>Format Checks:Submission format verified [ENO-C-1004524-30-00/F]</u>	<u>BC-CT002188-32</u>	Bananafly_killer	07/09/2018
<input type="checkbox"/>		Agency	<u>Format Checks:Submission format verified [ENO-C-1004531-31-00/F]</u>	<u>BC-KA002191-75</u>	Zeranol-pt2	07/09/2018
<input type="checkbox"/>		Agency	<u>Submission:Case rejected by ECHA due to expiration of Resubmission request [NAP-D-1004467-34-00/F]</u>	<u>BC-GJ002106-60</u>	Insecticide Product	29/08/2018

Agenda



R4BP 3 and SPC editor hands-on session	
	25 October 2018
11:30 – 11:45	Introduction to R4BP 3 and SPC editor
11:45 – 12:30	Exercise 1 (SPC for NA-APP, guided)
12:30 – 13:00	Exercise 2 (SPC for NA-MRS, individual)
13:00 – 14:00	Break
14:00 – 14:45	Exercise 3 (AS-APP, guided)
14:45 – 15:15	Exercise 4 (NA-APP, guided)
15:15 – 16:00	Exercise 5 (NA-MRS, individual)
16:00	END