

IT tools

Biocides Stakeholders' Day

24 September 2014

Jan Weber

Biocides Assessment Unit

European Chemicals Agency



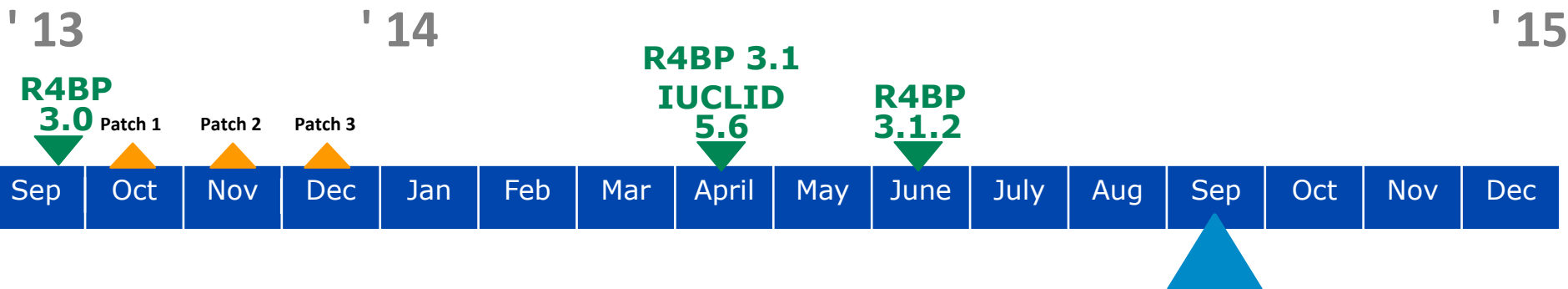
What's new

- 1. New R4BP 3 version**
2. New SPC
3. New SPC editor
4. IUCLID for biocides
5. New ECHA account management



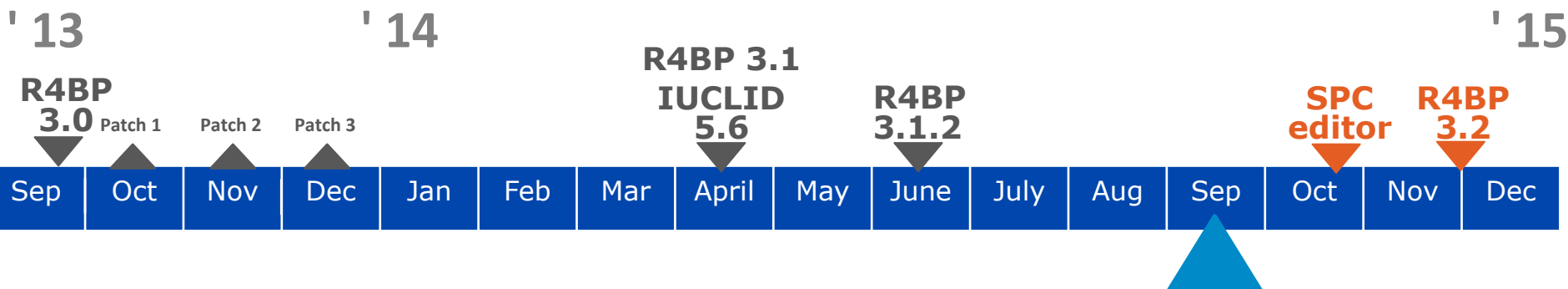
Where we are now

- R4BP 3.1.2
- IUCLID 5.6



Where we are going

- R4BP 3.2 in December
- SPC editor in October





R4BP 3.2: What to expect

- **SME verification**



R4BP 3.2: What to expect

- SME verification
- **Export search results**



R4BP 3.2: What to expect

- SME verification
- Export search results
- **Printing of case details**



R4BP 3.2: What to expect

- SME verification
- Export search results
- Printing of case details
- **Grouping of applications**



R4BP 3.2: What to expect

- SME verification
- Export search results
- Printing of case details
- Grouping of applications
- **Email alert to applicants**



R4BP 3.2: What to expect

- SME verification
- Export search results
- Printing of case details
- Grouping of applications
- Email alert to applicants
- **Nomination to consultants**



R4BP 3.2: What to expect

- SME verification
- Export search results
- Printing of case details
- Grouping of applications
- Email alert to applicants
- Nomination to consultants
- **Asset transfer among companies**



R4BP 3.2: What to expect

- SME verification
- Export search results
- Printing of case details
- Grouping of applications
- Email alert to applicants
- Nomination to consultants
- Asset transfer among companies
- **Migration of authorisation's relations from R4BP2**



R4BP 3.2: What to expect

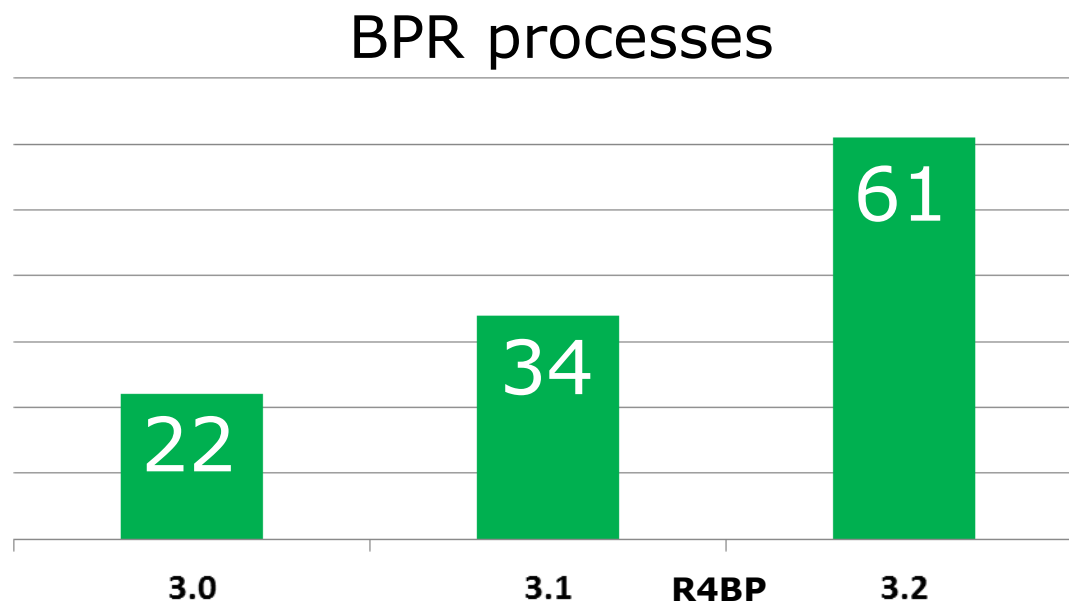
- Inclusion of active substance in Annex I
- Amendment of active substance in Annex I (COM initiated)
- Amendment of notification for placing on the market
- Cancellation of notification for placing on the market
- Cancellation of national authorisation
- Transfer of a national authorisation
- ...



+27
Processes
in total

R4BP 3.2: More for you

- More BPR processes
- Usability/productivity enhancements
- More ideas



What's new

1. New R4BP 3 version
- 2. New SPC**
- 3. New SPC editor**
4. IUCLID for biocides
5. New ECHA account management



A better SPC



Structure facilitates:

- R4BP 3 data processing
- Data dissemination
- Comparative assessment



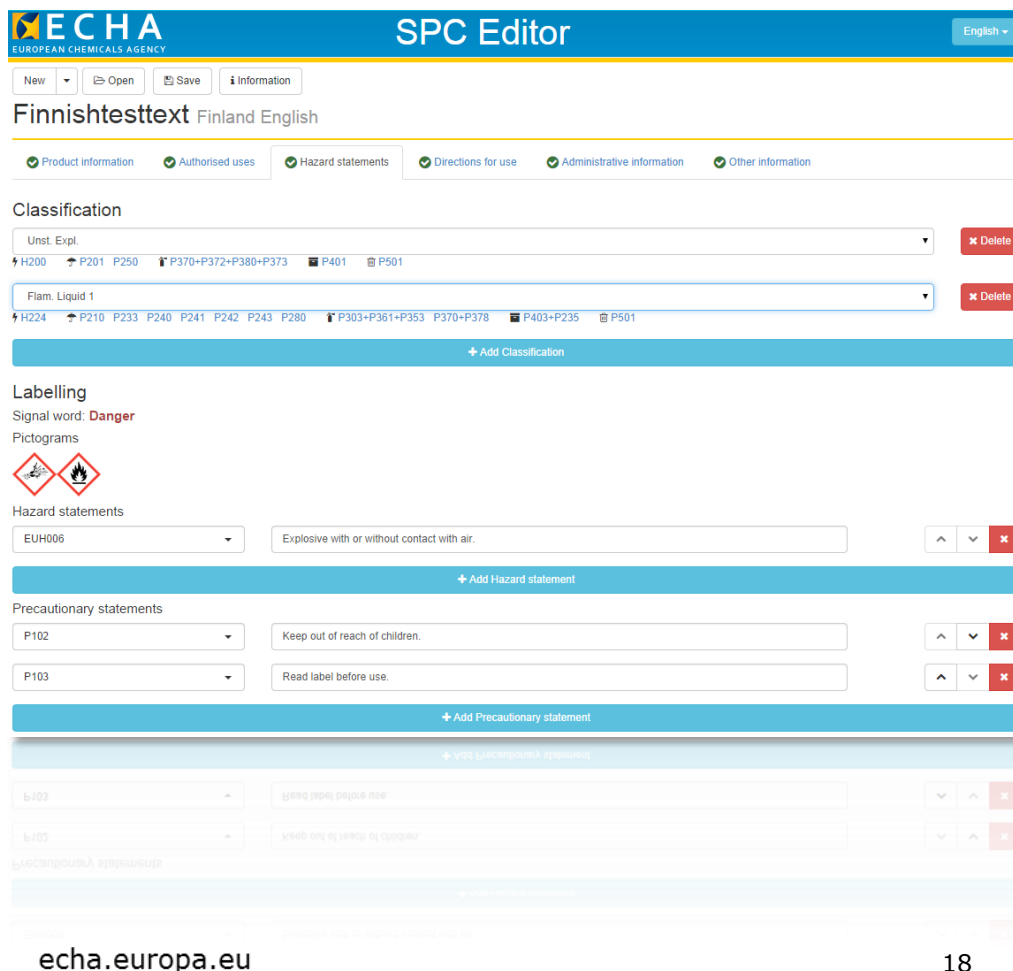
A better SPC

Stru

- **From R4BP 3.2 the new SPC format shall be used**
- Data dissemination
- Comparative assessment

The SPC editor

- Online tool
- Offline data
- Product
+
Family
- Languages



The screenshot shows the ECHA SPC Editor interface. At the top, there is the ECHA logo and the text "EUROPEAN CHEMICALS AGENCY". The main title is "SPC Editor" with a language dropdown set to "English". Below the title bar, there are buttons for "New", "Open", "Save", and "Information". The current document is titled "Finnishtesttext Finland English".

There are several tabs for different sections: "Product information", "Authorised uses", "Hazard statements", "Directions for use", "Administrative information", and "Other information". The "Hazard statements" tab is currently active.

The "Classification" section shows two entries:

- Unst. Expl. (H200, P201, P250, P370+P372+P380+P373, P401, P501) with a "Delete" button.
- Fam. Liquid 1 (H224, P210, P233, P240, P241, P242, P243, P280, P303+P361+P353, P370+P378, P403+P235, P501) with a "Delete" button.

A blue bar with "+ Add Classification" is located below the classification entries.

The "Labelling" section shows a signal word of "Danger" and two pictograms: a flame and a gas cylinder.

The "Hazard statements" section shows one entry: EUH006 (Explosive with or without contact with air.) with a "Delete" button.

A blue bar with "+ Add Hazard statement" is located below the hazard statements.

The "Precautionary statements" section shows two entries: P102 (Keep out of reach of children.) and P103 (Read label before use.) with "Delete" buttons.

A blue bar with "+ Add Precautionary statement" is located below the precautionary statements.

At the bottom of the interface, there is a footer with the URL "echa.europa.eu" and the page number "18".

The SPC editor

The structured information can be printed according to the published SPC template

Summary of product characteristics for a biocidal product

1. Administrative information

1.1. Trade names of the product

| Market area | Trade name |
|-------------|---------------|
| Finland | Trade Company |

1.2. Manufacturers of the product

| Name of the manufacturer | Manufacturer Company |
|---------------------------------|---------------------------------------|
| Address of the manufacturer | Mannerheimintie 230245HelsinkiFinland |
| Location of manufacturing sites | Mannerheimintie 54035014 |

1.3. Manufacturer(s) of the active substance(s)

| Name of the manufacturer | Manufacturer Company |
|---------------------------------|----------------------------|
| Address of the manufacturer | Kalevankatu 328765Helsinki |
| Location of manufacturing sites | Kalevankatu 459876Helsinki |

2. Product composition and formulation

2.1. Qualitative and quantitative information

| BAS number | EC number | CAS number | Common name |
|------------|-----------|------------|---------------------|
| 1331 | 217-129-5 | 1746-81-2 | Mordimuron ethiltri |

CL - Contact liquid or gel

3. Authorised use(s)

Use #1 4 use#*


| Product type | PT01 - Human hygiene (Disinfectants) |
|--|---|
| Where relevant, an exact description of the authorised use | Finnistesttext description |
| Fields of use | Indoor |
| Category(ies) of users | General public (non-professional) |
| Target organisms | Scientific name Bacillus spp. Common name Bacillus bacillus |
| Application method(s) | Development stage early |
| Application rate(s) and frequencies | Use methods detailed methods |
| Pack sizes and packaging material | Dose: Twice a week Duration: 43% |
| Instructions for the use | Timing: 2 x 1 Size Type Material 1 liter bottles glass isyfsssoobrem,/ |

4. Hazard and precautionary statements

4.1. Classification

Unst. Exp.

4.2. Labelling

| Signal word | Danger |
|--------------------------|---|
| Pictograms |  |
| Hazard statements | Explosive with or without contact with air. |
| Precautionary statements | Keep out of reach of children. Read label before use. |

5. Directions for use

5.1. Particulars of likely direct or indirect effects

ijhghyuiop.kjghf

5.2. First aid instructions

oityreasdfghjkl.mnbvcxd

5.3. Emergency measures to protect the environment

oityreasdfghjkl.mnbvcxd

5.4. Instructions for safe disposal of the product and its packaging

oityreasdfghjkl.mnbvcxd

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

oityreasdfghjkl.mnbvcxd

6. Other information

ijhghf

To use the SPC editor

Verify you browser version

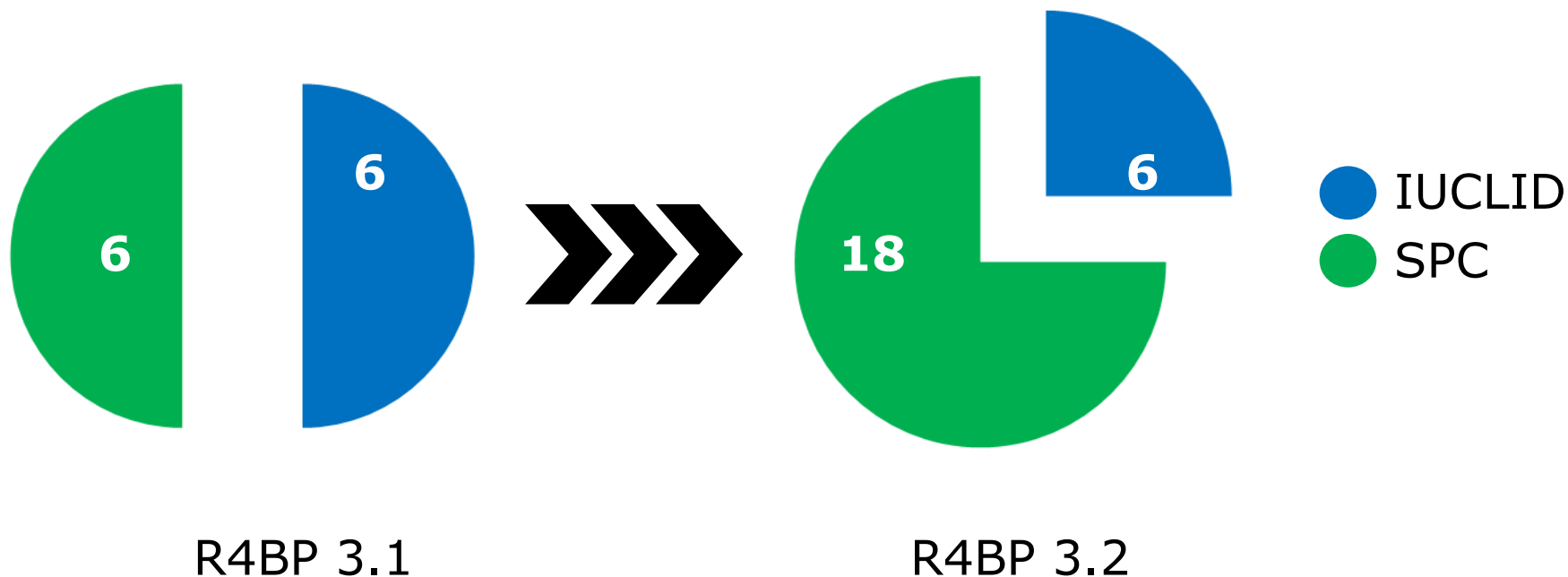
MS Internet Explorer v.10+

Mozilla Firefox v.29+

Google Chrome v.35+

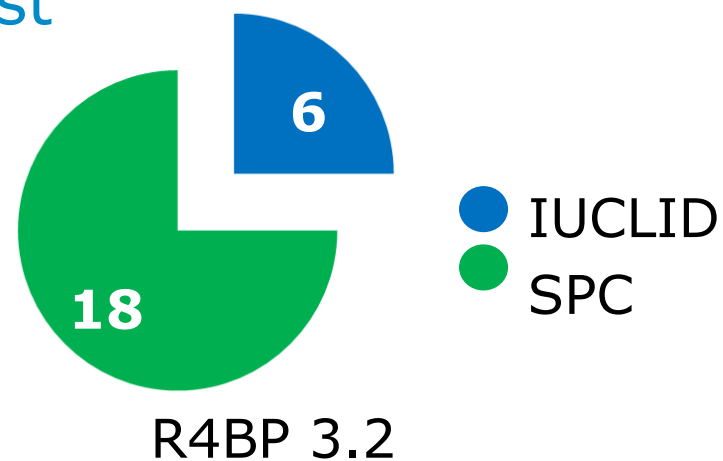


Applications for biocidal products: SPC & IUCLID



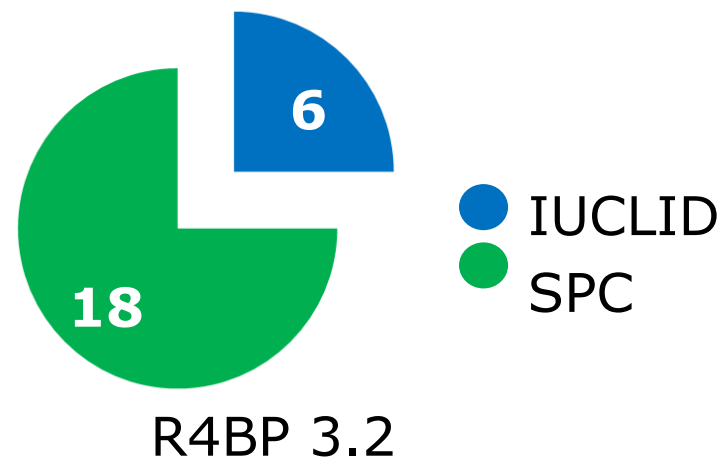
Applications for biocidal products: SPC & IUCLID

- National authorisation
- Provisional national authorisation
- Amendment of national authorisation
- Simplified authorisation
- Notification of experiment or test
- Union authorisation



Applications for biocidal products: SPC & IUCLID

- Simplified authorisation same biocidal product
- Simplified authorisation changes on request
- Union authorisation same biocidal product (pending)
- Pre-submission for Union authorisation
- Merge of product authorisations in one product family
- ...



Migration R4BP2 → R4BP 3

- Incorrect data in R4BP2 will compromise the migration or have negative consequences on the use of the migrated authorisations
- **MSCA:** product name, trade names, production site, authorisation dates
- **DG Environment:** R4BP2 account holder and authorisation holder details
- Swiss authorisations – not yet available



Migration R4BP2 → R4BP 3

- Incorrect data in R4BP2 will compromise the migration or have negative consequences on migrated authorisations

The company identifier used in R4BP 3 is crucial information to be indicated in R4BP2

- DG... authorisation... r and
- Swiss authorisations – not yet available e



Solve migration issues

If your authorisation is still only in R4BP2:

- 1. Contact the evaluating CA**
- 2. Contact DG Environment**
- 3. Contact ECHA**



What's new

1. New R4BP 3 version
2. New SPC
3. New SPC editor
- 4. IUCLID for biocides**
5. New ECHA account management



IUCLID 5

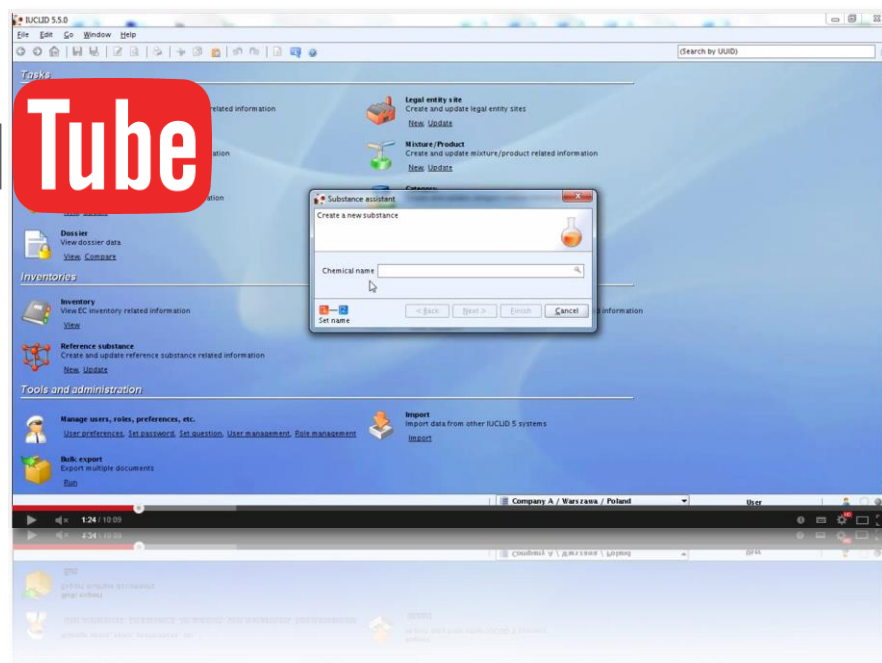


- BPR dossier creation supported since version 5.5
- Mandatory format for scientific data:
 - Reporting of the (robust) summaries from studies performed on biocidal products, active substances and other product components (in a **structured** and **electronic** way, **harmonised** at the OECD level)

IUCLID 5 support

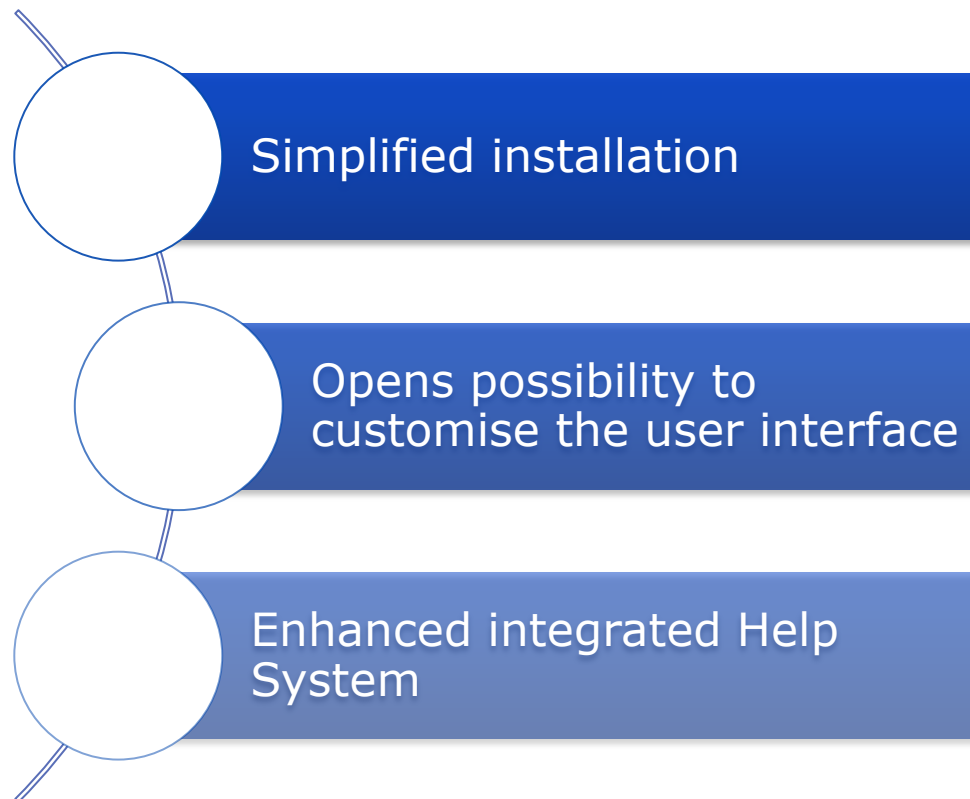
- Manuals
 - On ECHA's website
 - On IUCLID website
- Video tutorials on IUCLID website

YouTube





- Technical upgrade ongoing
- Update to the latest versions of the OECD Harmonised Templates in 2015
- IUCLID 6 will be used for submissions to ECHA **from 2016**



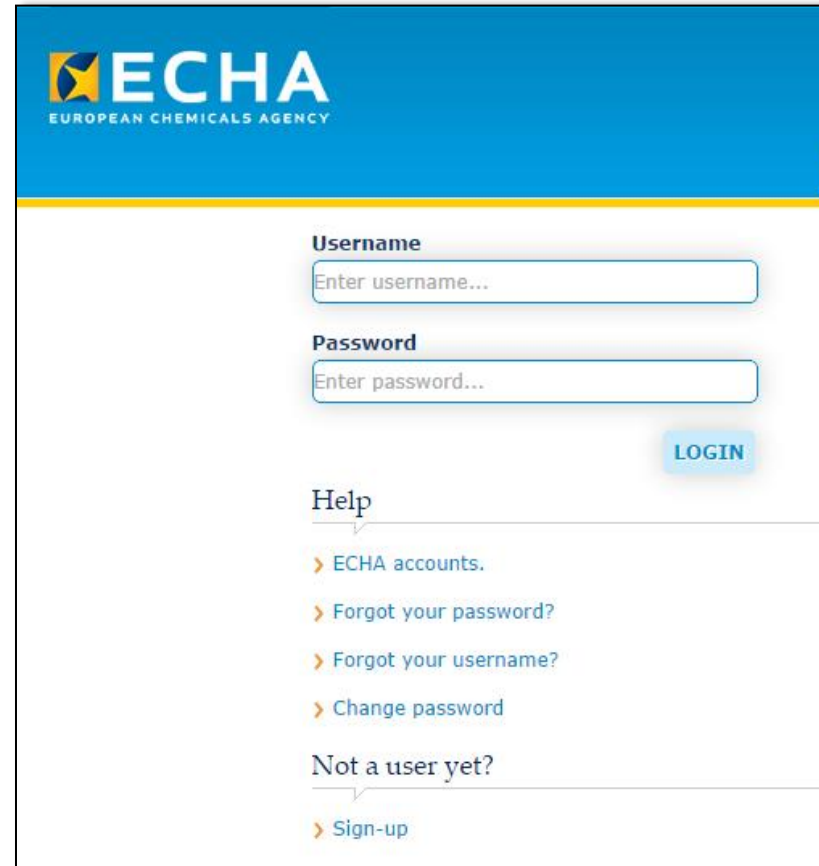
What's new

1. New R4BP 3 version
2. New SPC
3. New SPC editor
4. IUCLID for biocides
- 5. New ECHA account management**



Account management

- Single sign-in for all ECHA tools
- Smooth transition



The screenshot shows the ECHA account management interface. At the top, there is a blue header with the ECHA logo and the text "EUROPEAN CHEMICALS AGENCY". Below the header, there are two input fields: "Username" with the placeholder text "Enter username..." and "Password" with the placeholder text "Enter password...". To the right of the password field is a blue "LOGIN" button. Below the login fields, there is a "Help" section with a dropdown arrow. The help menu is open, showing a list of links: "ECHA accounts.", "Forgot your password?", "Forgot your username?", and "Change password". Below the help section, there is a "Not a user yet?" section with a dropdown arrow. The menu is open, showing a link: "Sign-up".

Get ready for SPC editor and R4BP 3.2

- Update your browser
- The new SPC Editor will be available in October
- Read the manuals

Thank you

jan.weber@echa.europa.eu

Subscribe to our news at
echa.europa.eu/subscribe

Follow us on Twitter
[@EU_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook
[Facebook.com/EUECHA](https://www.facebook.com/EUECHA)

