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
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A better SPC

Structure facilitates:

• R4BP 3 data processing

• Data dissemination

• Comparative assessment
A better SPC

Structure facilitates:

• R4BP 3 data processing
• Data dissemination
• Comparative assessment

From R4BP 3.2 the new SPC format shall be used
The SPC editor

- Online tool
- Offline data
- Product + Family
- Languages
The SPC editor

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

R4BP 3.1

- IUCLID: 6
- SPC: 6

R4BP 3.2

- IUCLID: 6
- SPC: 18
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
- ...

R4BP 3.2

IUCLID

SPC

6

18
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 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.

The company identifier used in R4BP 3 is crucial information to be indicated in R4BP2.
Solve migration issues

If your authorisation is still only in R4BP2:

1. Contact the evaluating CA
2. Contact DG Environment
3. Contact ECHA
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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
• 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

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4. IUCLID for biocides
5. New ECHA account management
Account management

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

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