

IT tool developments: R4BP 3 and Summary of Product Characteristics (SPC) editor

Biocides Stakeholders' Day

1 September 2016

Roberto Gilioli
Biocides Assessment Unit
European Chemicals Agency



Updated IT tools to help you

1. What is now available?
2. Coming soon
3. Looking ahead

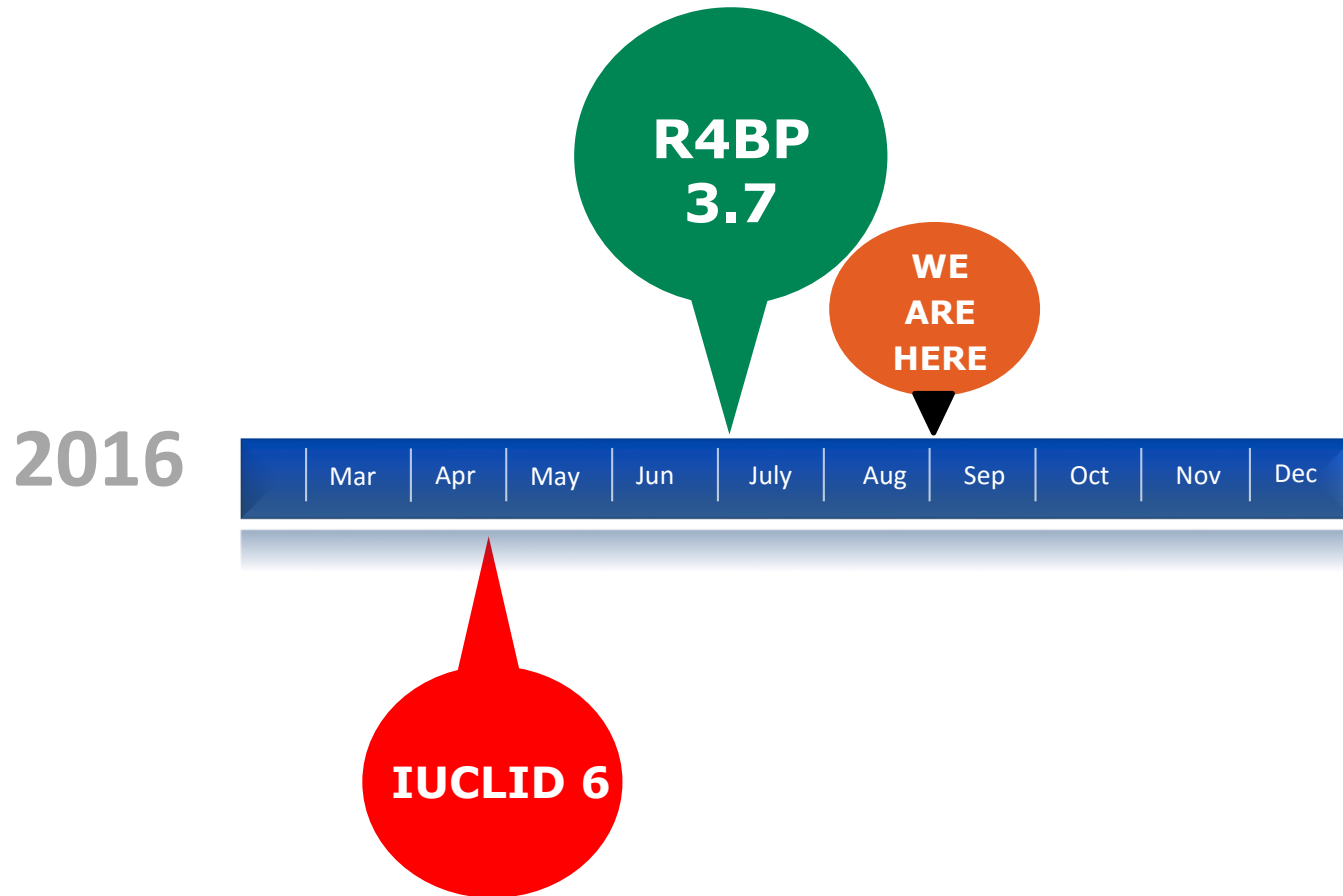


Updated IT tools to help you

- 1. What is now available**
2. Coming soon
3. Looking ahead



R4BP 3.7 - more features available



New Review Programme features

- Declare interest to notify
- Notify
- Add new active substance and product-type combinations
- Manage the list of participants
 - Add and remove participants
 - Take over the role of participant

Use IUCLID 6

- R4BP 3 only accepts IUCLID 6 files for your submissions and re-submissions
- Make sure you prepare your dossier with the right IUCLID format

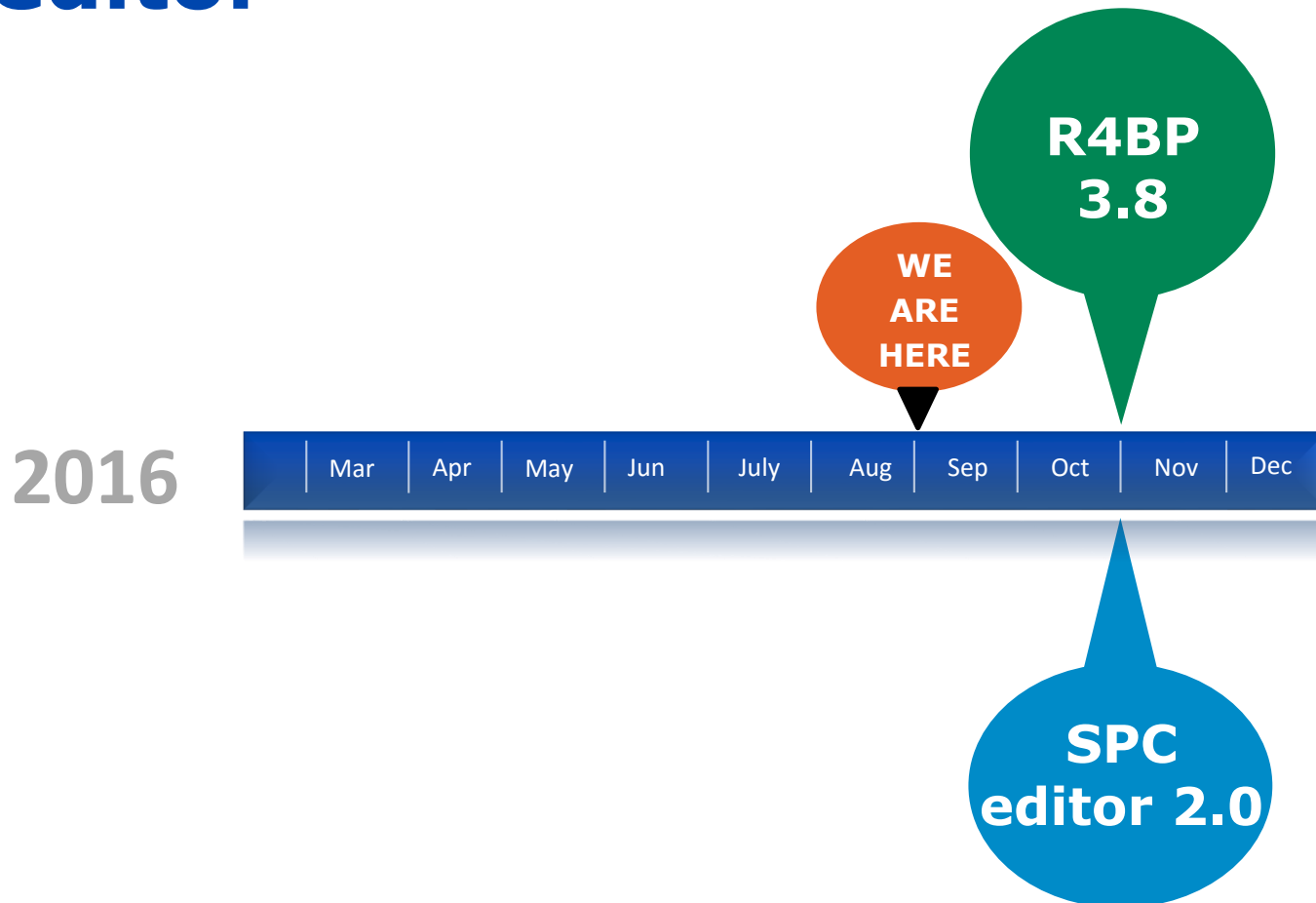
<https://iuclid6.echa.europa.eu/>

Updated IT tools to help you

1. What is now available?
- 2. Coming soon**
3. Looking ahead



New versions of R4BP 3 and SPC editor



SPC editor 2.0

Improved management
of data for product families



Example: mosquito insecticides

A company places on the market a **portfolio of insecticide products** with:

- **Same active substances** with a similar composition (within specified variations)
- **Similar levels of risk and efficacy**
- **Similar uses**: spray for consumers and spray fumigator for professional use

→ You can save time and money by grouping the products into one 'family' application instead of submitting multiple requests for single authorisations

Subgroups in the example family

Sprays

- Insecticides
- Consumer use
- Instructions: store in a cool place



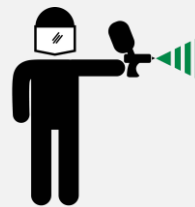
Spray 1



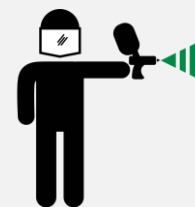
Spray 2

Fumigators

- Insecticides
- Professional use
- Instructions: wear PPE



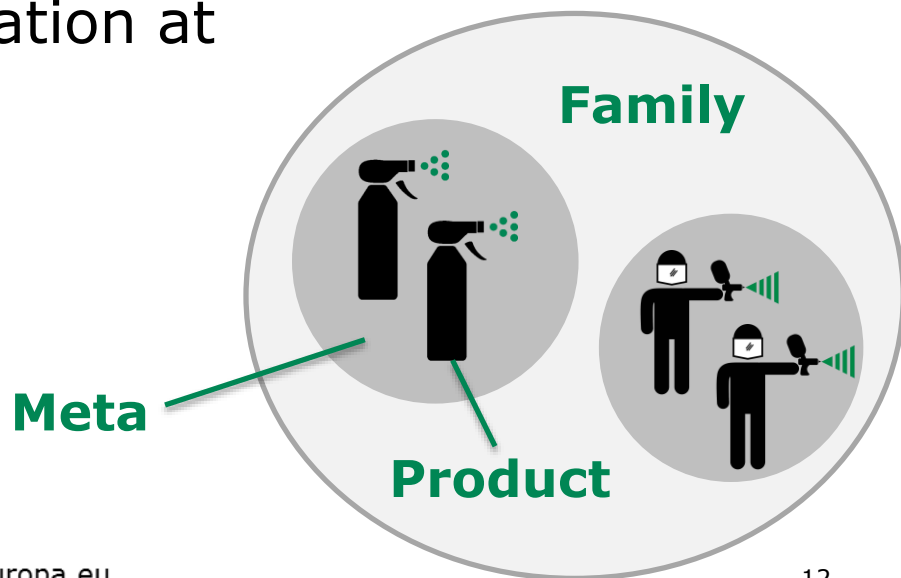
Fumigator 1



Fumigator 2

Fill in 3 levels of information in the tool

- 1. Family:** general information that applies to all the products
- 2. Meta:** formulation type, authorised uses, risk management measures and hazard and precautionary statements common to the products
- 3. Product:** specific information at product level



SPC editor improvements

- Update your product family easily:
 - ✓ Create and delete meta SPCs and products
 - ✓ Duplicate meta SPCs and products
- Re-use data for your future applications
 - ✓ Mutual recognitions
 - ✓ Same biocidal products
 - ✓ Notifications



Migration of already submitted SPCs

- After R4BP October update, the tool will only accept family SPCs in the new format
- All (old format) family SPCs in R4BP 3 will be automatically migrated to the new format
- No data will be lost



R4BP 3.8

More flexibility



New Union authorisation features

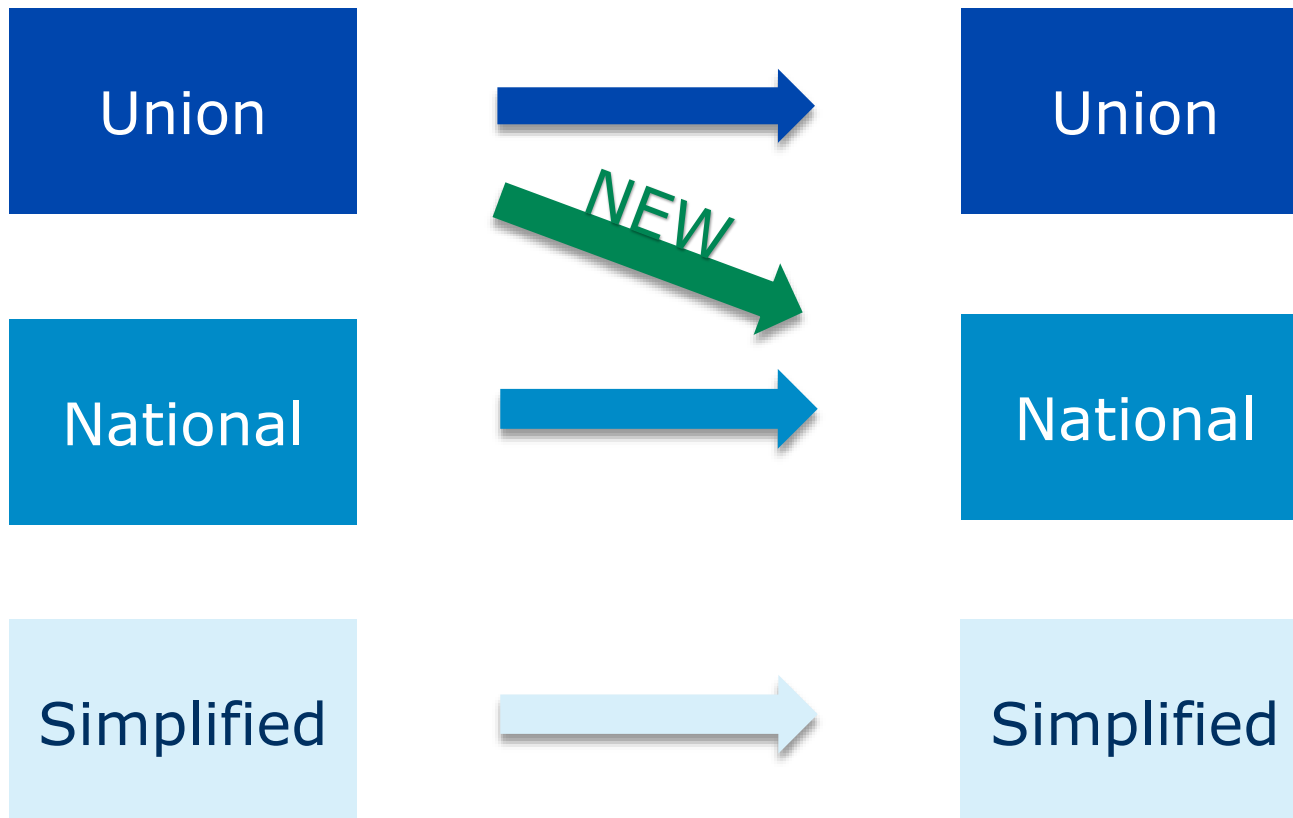
- Request minor, major and administrative changes
- Transfer assets
- Make amendments (SPC update, expiry date, documents)
- Notify a product in a product family
- Request to cancel your authorisation

New opportunities with same biocidal product regulation update

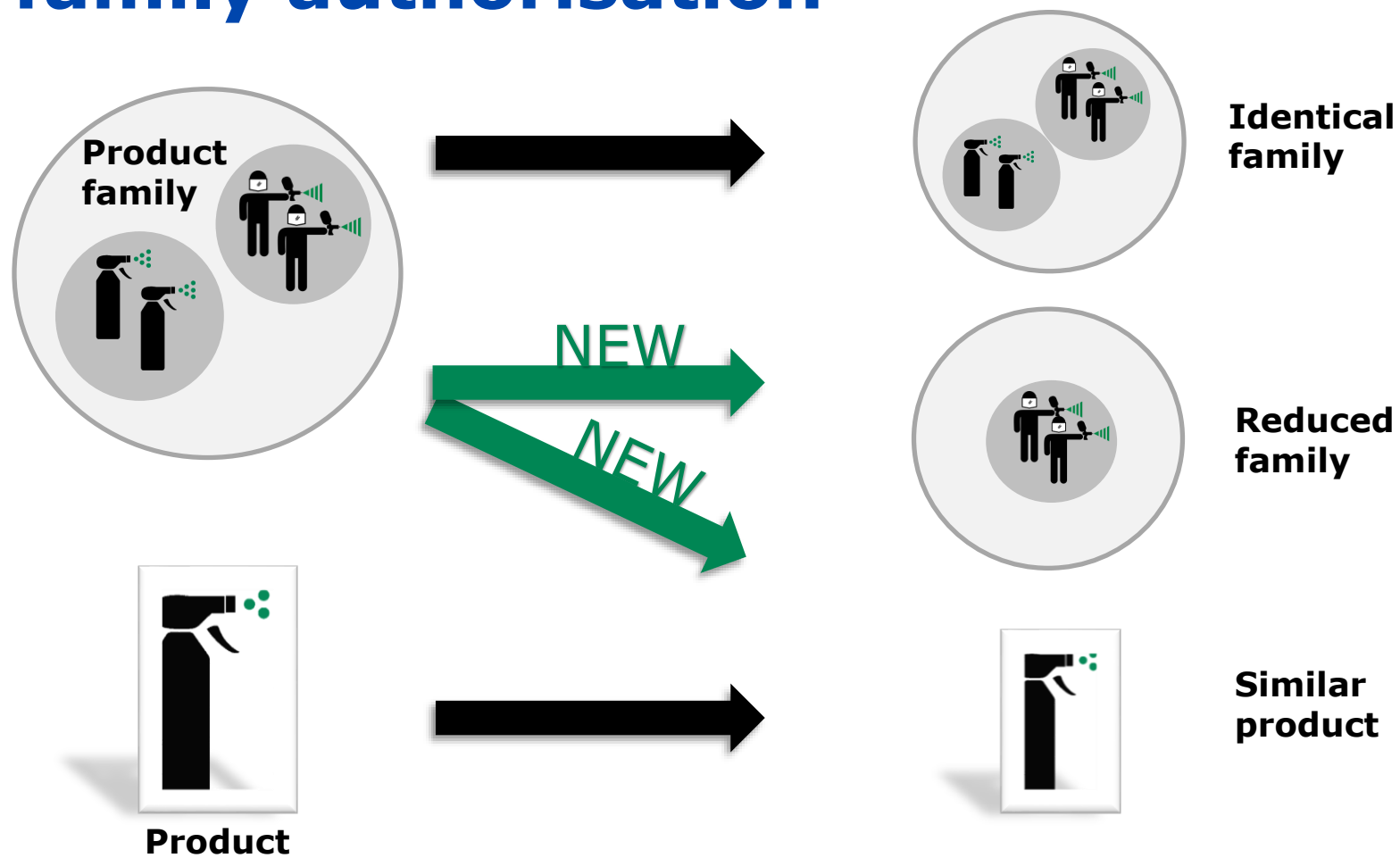
- ✓ Get a national authorisation based on an existing Union authorisation
- ✓ Get an authorisation for a single product, or a reduced family, based on an existing product family authorisation



National authorisation based on Union authorisation



Product authorisation based on family authorisation



Example: company need in a specific market

Sprays

- Insecticides
- Consumer use
- Instructions: store in a cool place



Spray 1



Spray 2

Authorisation of
same products



Your company would
like to re-brand a **set of
sprays for consumers**

Example: company need in a specific market

Sprays

- Insecticides
- Consumer use
- Instructions: store in a cool place



Spray 1



Spray 2

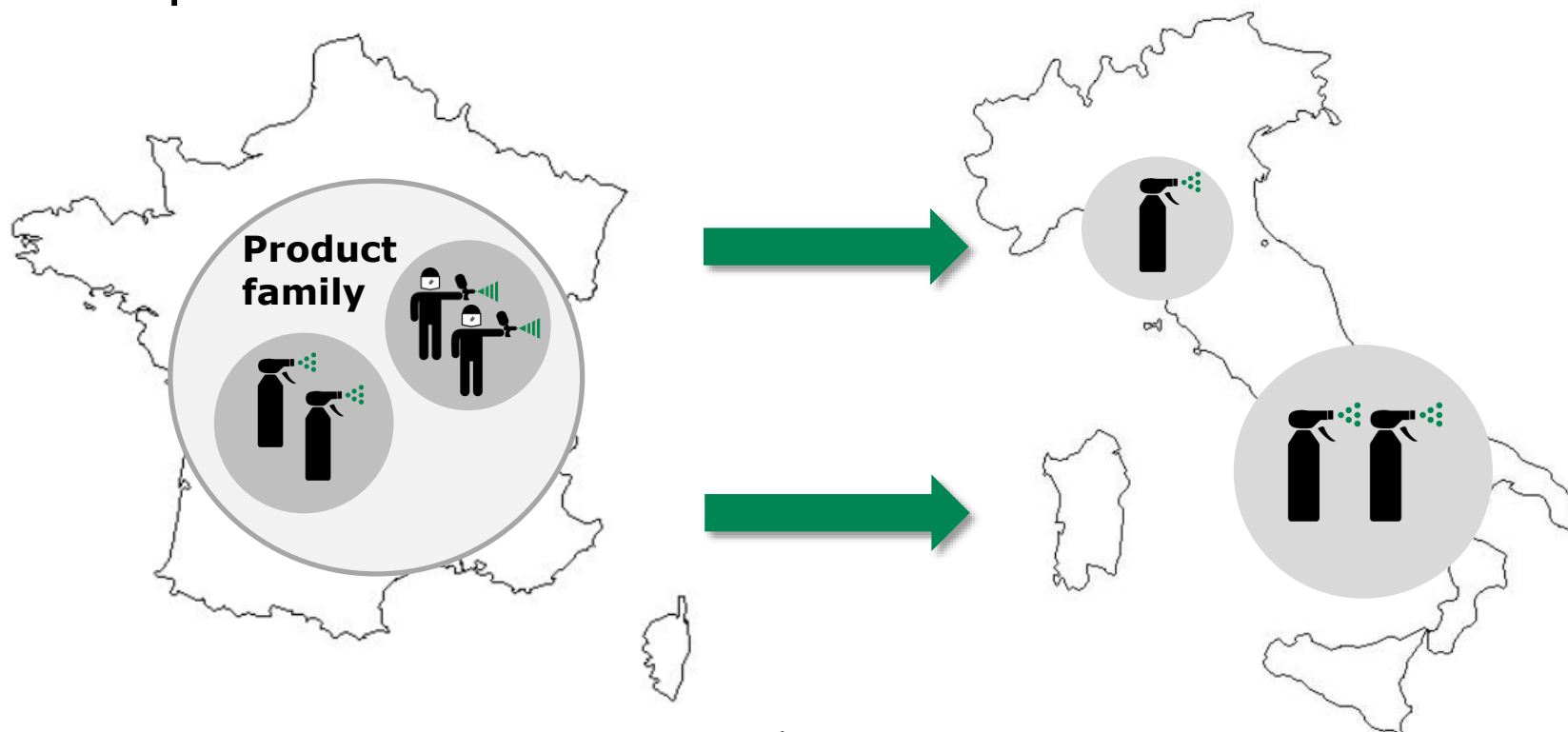
Authorisation of
same products



Your company would like
to re-brand **one spray
product** for consumers

Simplified authorisation

Notify a **single product** to another market when it belongs to a product family that already has a simplified authorisation



Updated IT tools to help you

1. What is now available?
2. Coming soon
- 3. Looking ahead**



Next steps

- Implement remaining (minor) processes
- Enable data correction requests
- Enhance flexibility (bulk actions, case transfers)
- Improve user interface
- Improve communication functionalities
- Add functionalities to support comparative assessment



We need your feedback

- Your feedback is key to make the tools easier, more flexible and effective
- Send your issues and proposals for improvement to ECHA Helpdesk
- We are here to help





Supporting material

- + About Us
- Regulations
 - + REACH
 - + CLP
 - Biocidal Products Regulation
 - > Understanding BPR
 - > Upcoming deadlines
 - + Approval of active substances
 - Authorisation of biocidal products
 - > National authorisation and mutual recognition
 - + Union authorisation
 - + National authorisation and mutual recognition renewal
 - + Simplified authorisation
 - + Technical equivalence
 - > In situ generated active substances

Authorisation of biocidal products

All biocidal products must get an authorisation before they can be made available on the market. Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it.



National authorisation and mutual recognition

If the product will be placed only on a single market, authorisation from that country is sufficient.

If a company wishes to place the product on the market in several countries, it can apply for mutual recognition for the product authorisation.



National authorisation and mutual recognition renewal

Renewal of a national authorisation as an application by an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types.



Union authorisation

The Biocidal Products Regulation introduces a new alternative for companies that wish to apply for an EU-wide authorisation in one go.

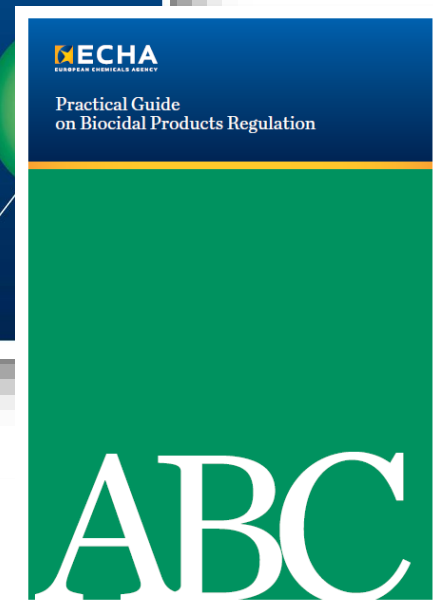
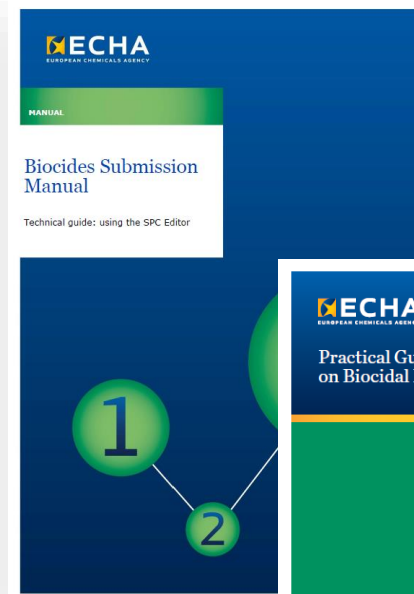


Simplified authorisation

There is also a simplified procedure for products which meet certain criteria specified in the regulation, e.g. do not contain any substances of concern.

Same biocidal product authorisation

There is the possibility to apply for an authorisation of a biocidal product, which is either identical to an already authorised biocidal product or identical to a biocidal product for which an application for authorisation is ongoing.



Thank you!

roberto.gilioli@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)

