![ECHA - European Chemicals Agency logo]

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

Biocides Stakeholders' Day

1 September 2016

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Updated IT tools to help you
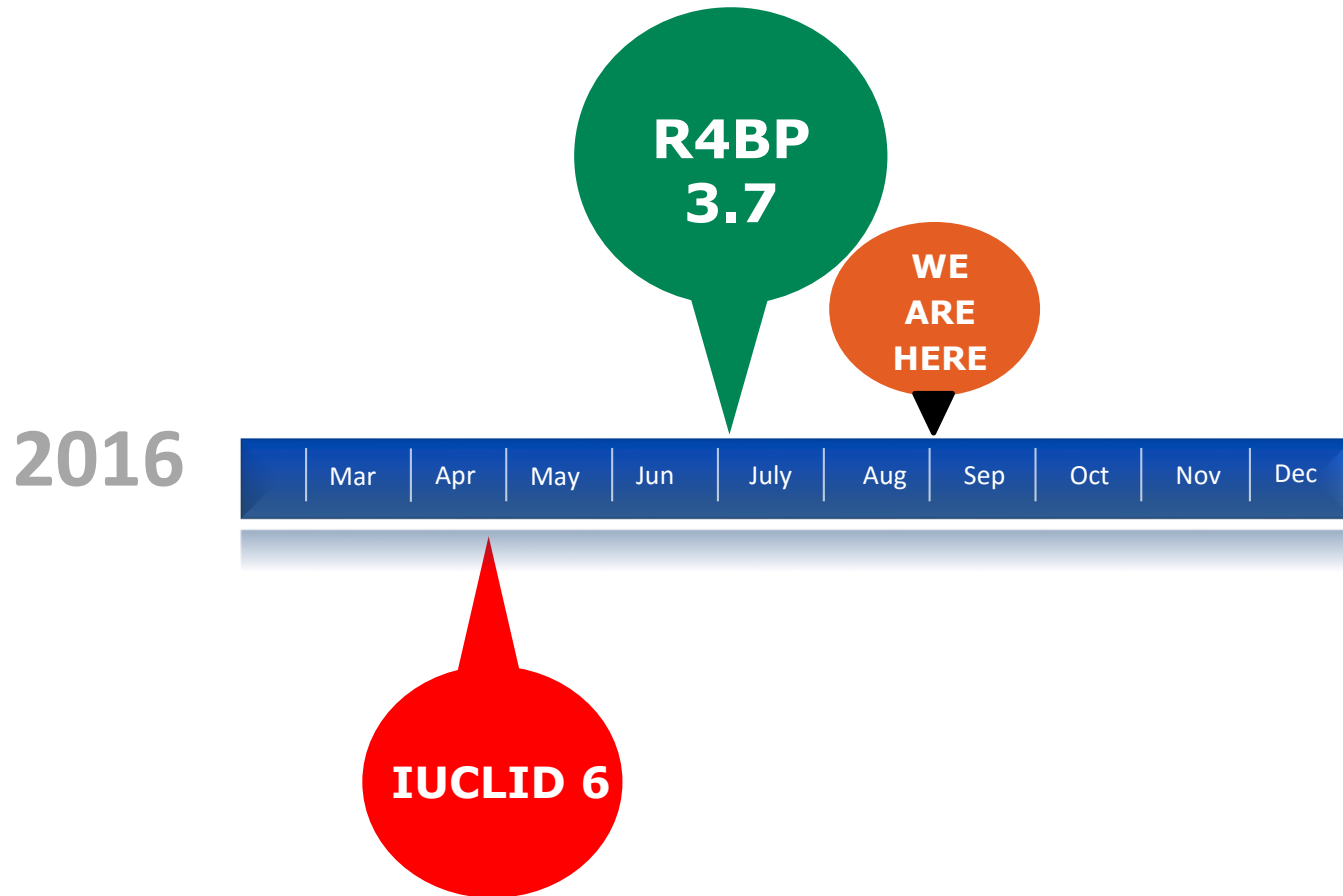
1. What is now available?

2. Coming soon

3. Looking ahead

Updated IT tools to help you

1. What is now available

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R4BP 3.7 - more features available

R4BP 3.7

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2016

| Mar | Apr | May | Jun | July | Aug | Sep | Oct | Nov | Dec |

IUCLID 6

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

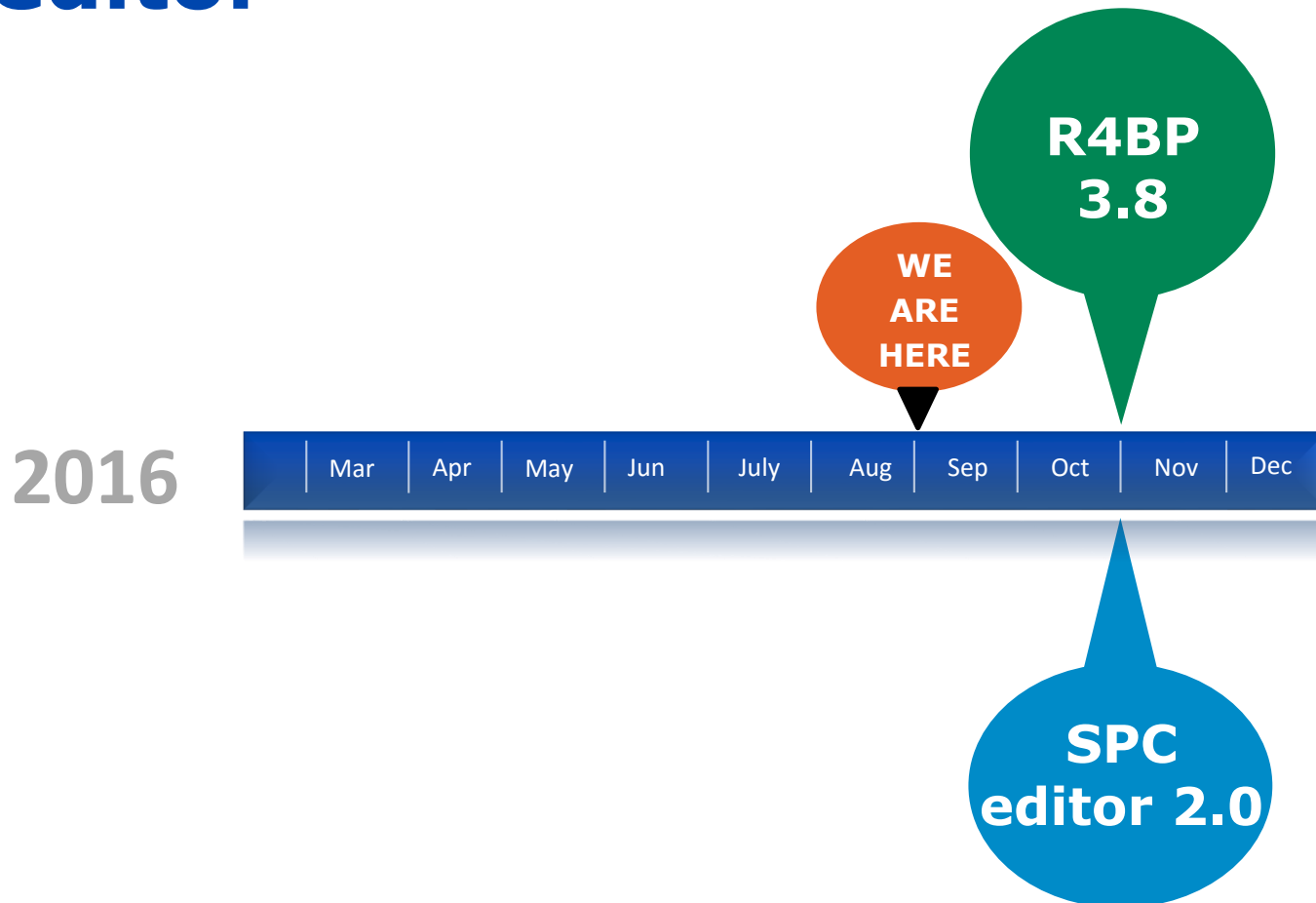- Make sure you prepare your dossier with the right IUCLID format

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

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New versions of R4BP 3 and SPC editor

2016 — Mar | Apr | May | Jun | July | Aug | Sep | Oct | Nov | Dec

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R4BP 3.8

SPC editor 2.0

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
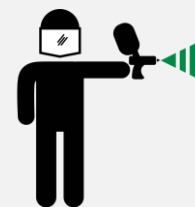- Consumer use
- Instructions: store in a cool place

Spray 1   **Spray 2**

Fumigators

- Insecticides
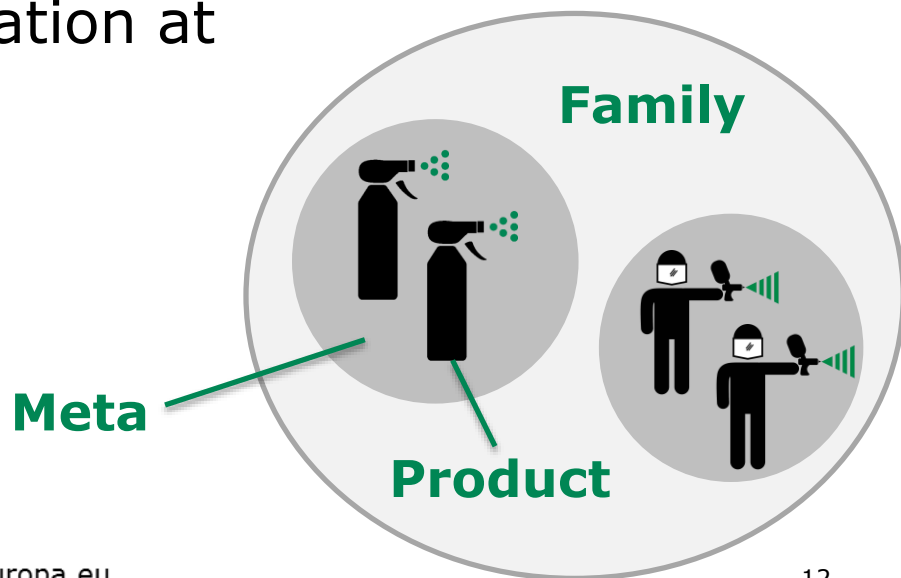- Professional use
- Instructions: wear PPE
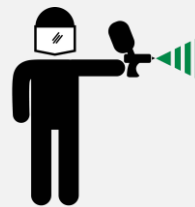
Fumigator 1 Fumigator 2

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

Union	→	Union
	NEW ↘	
National	→	National
Simplified	→	Simplified
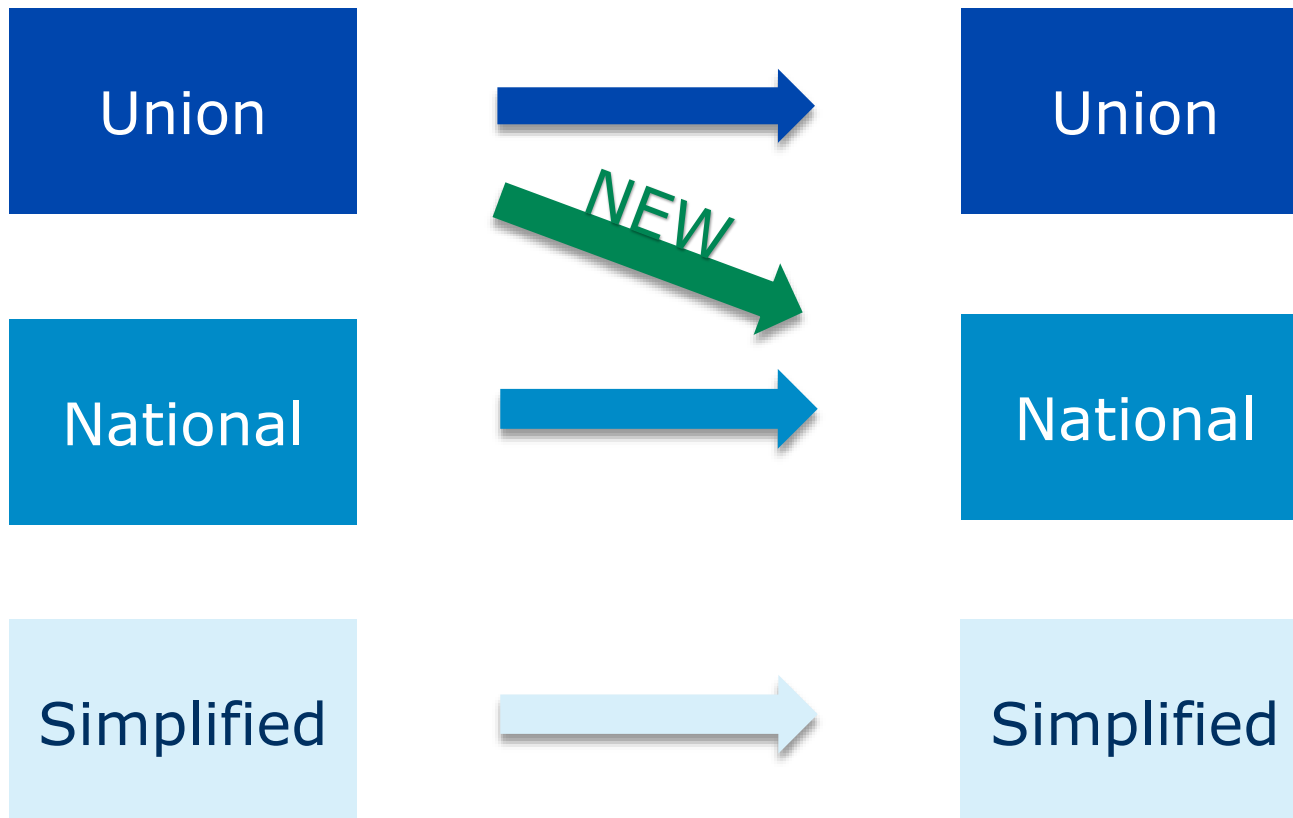
Product authorisation based on family authorisation
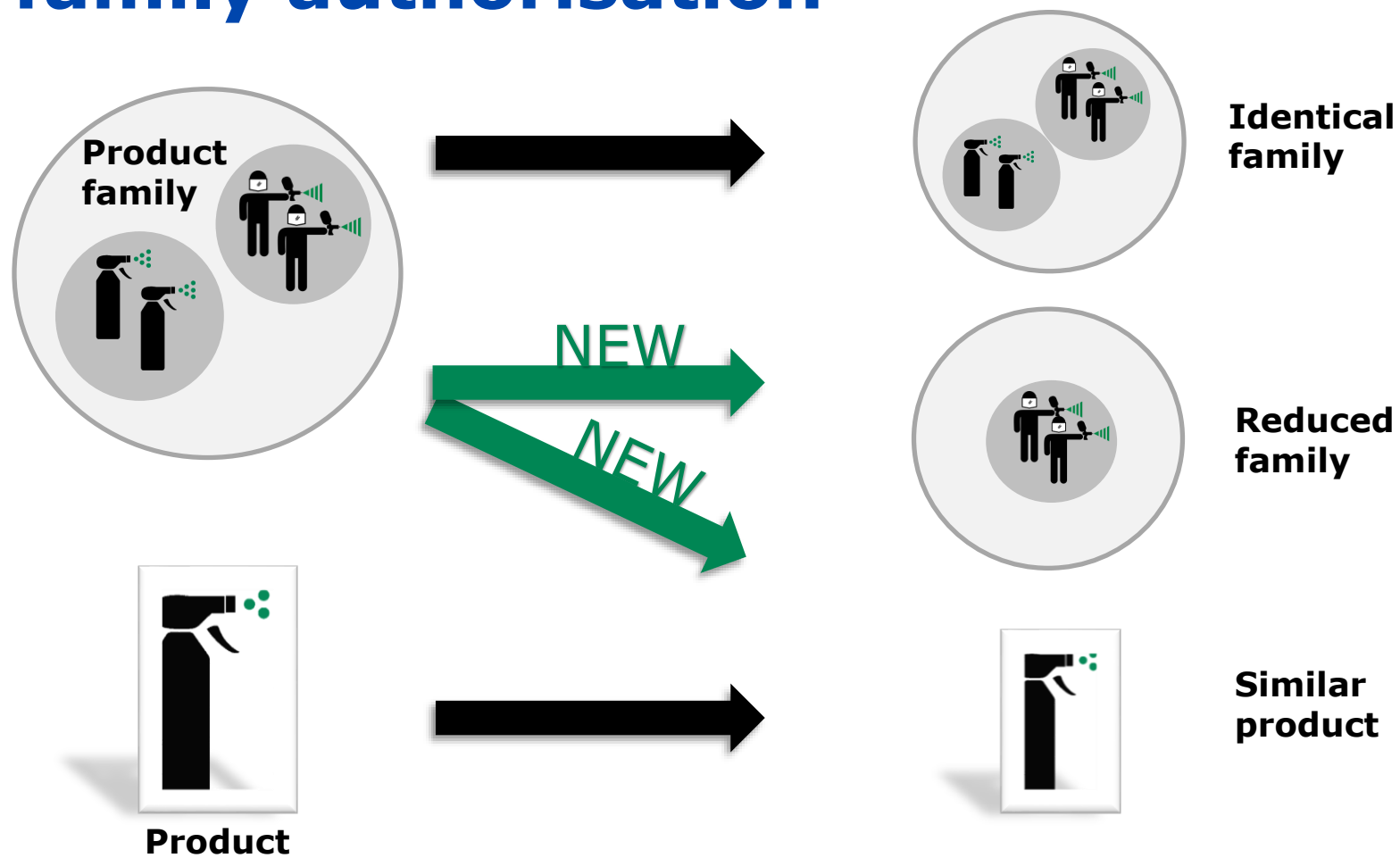
Product family

Identical family

NEW

Reduced family

NEW

Product

Similar product

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
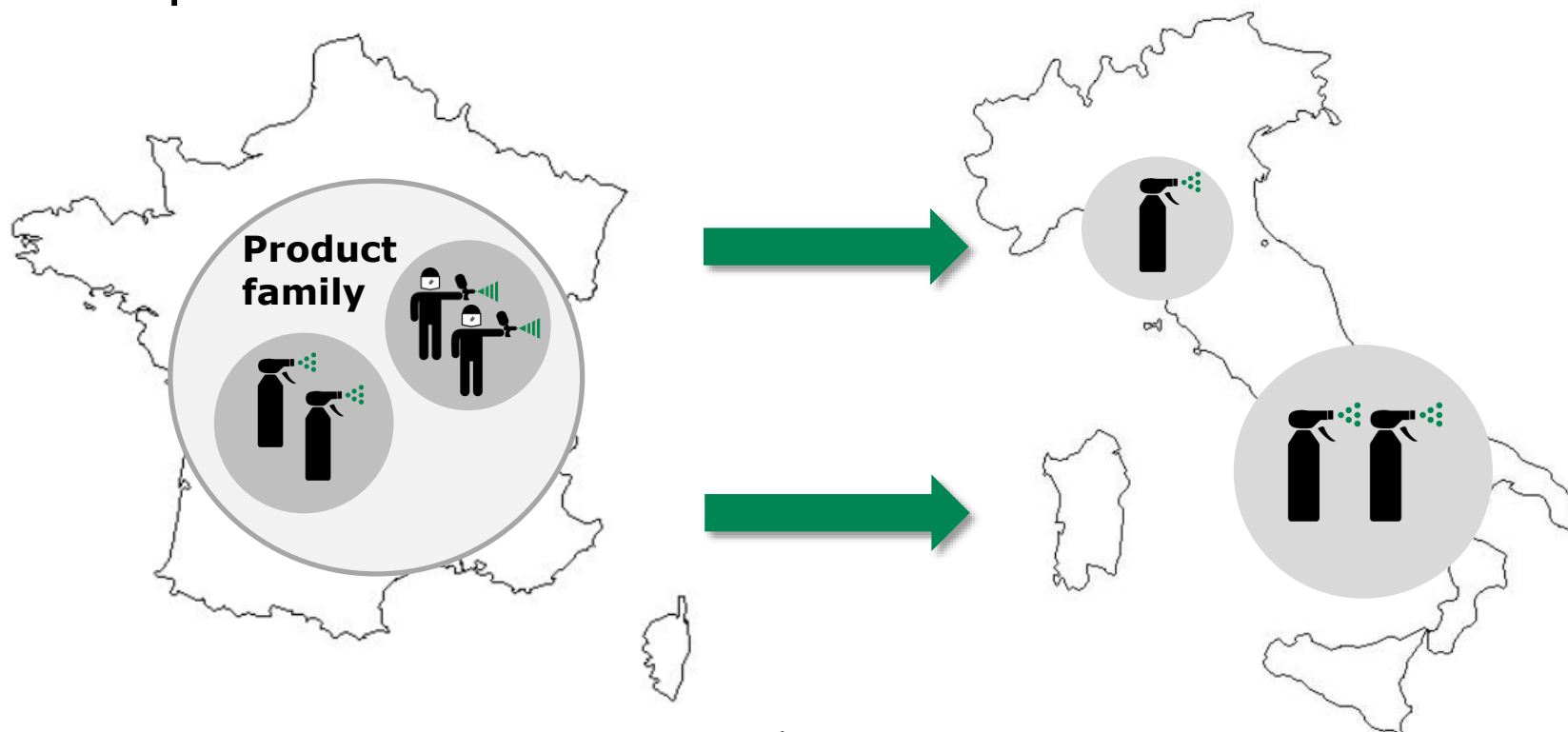
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Next steps

- 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

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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

Thank you!

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