# Same Biocidal Product Regulation and R4BP 3

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# Content

- Amendments to the Same Biocidal Products Regulation
- New features in R4BP 3

# Same Biocidal Products Regulation

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/1802**

**of 11 October 2016**

**amending Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council**

**(Text with EEA relevance)**

# New SBP Regulation

- From product family to single product
- From Union to national authorisation

# From family to single product

The Same Biocidal Product Regulation (SBP) has been amended to clarify beyond doubt that an **individual product** covered under a **biocidal product family** authorisation is also eligible as related reference product to obtain **single biocidal product authorisation**

Available for Union, national and simplified authorisations – **not for mutual recognitions**

# From Union to national authorisation

To respond to the needs of companies, in particular SMEs, the new SBP Regulation gives the possibility to apply for **national authorisations** of same products

…where the related reference product has been authorised by **Union authorisation (authorised)**

or

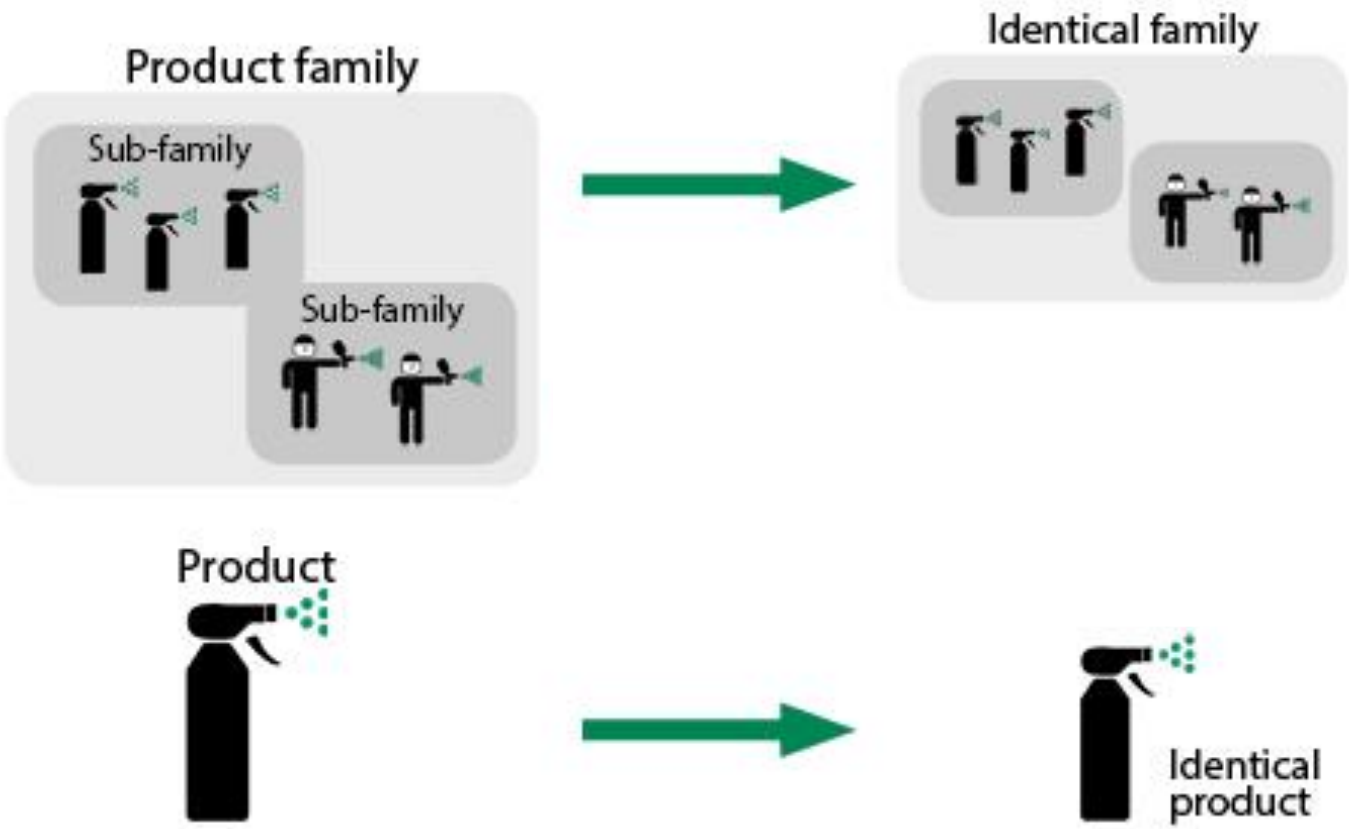
…is the subject of an application for such an authorisation **(pending)**

# Benefits to small businesses

- New business opportunities to go from wider to narrower markets:
  - From family to reduced family or single product (using the new meta-SPC)
  - From  Union to national authorisation

In “sequence-authorised”, or in “parallel-pending”

# New options with the new family structure



# What is required to apply?

- **Authorisation number** (authorised) or **application number** (pending) in R4BP 3
- Indication of the **proposed differences** in the products (only administrative changes – see Title I of the annex to **Regulation 354/2013**) and evidence that the products are identical on all other aspects (same authorisation conditions)
- Where required, **letters of access** to all the data supporting the authorisation of the related reference product (e.g. delegated assets)
- Draft **summary of product characteristics** for the 'same' product

# How are ‘same’ products linked?

- The ‘same’ product will have a **different authorisation number** than the reference product

- R4BP 3 will show the **link** between same products and related reference products

- Authorisations of the ‘same’ product or the related reference product **can be changed or cancelled** in R4BP 3 **independently** from each other

# How to apply?

- Apply in R4BP 3 (no IUCLID 6 file is required)
- National authorisation: application to the **same MSCA** who authorised the reference product
- Simplified authorisation: application to the **same MSCA** who authorised the reference product
- Union authorisation: application to **ECHA**
- National authorisation based on Union authorisation: application to the **MSCA** of the chosen market

# ECHA's role

Opinions

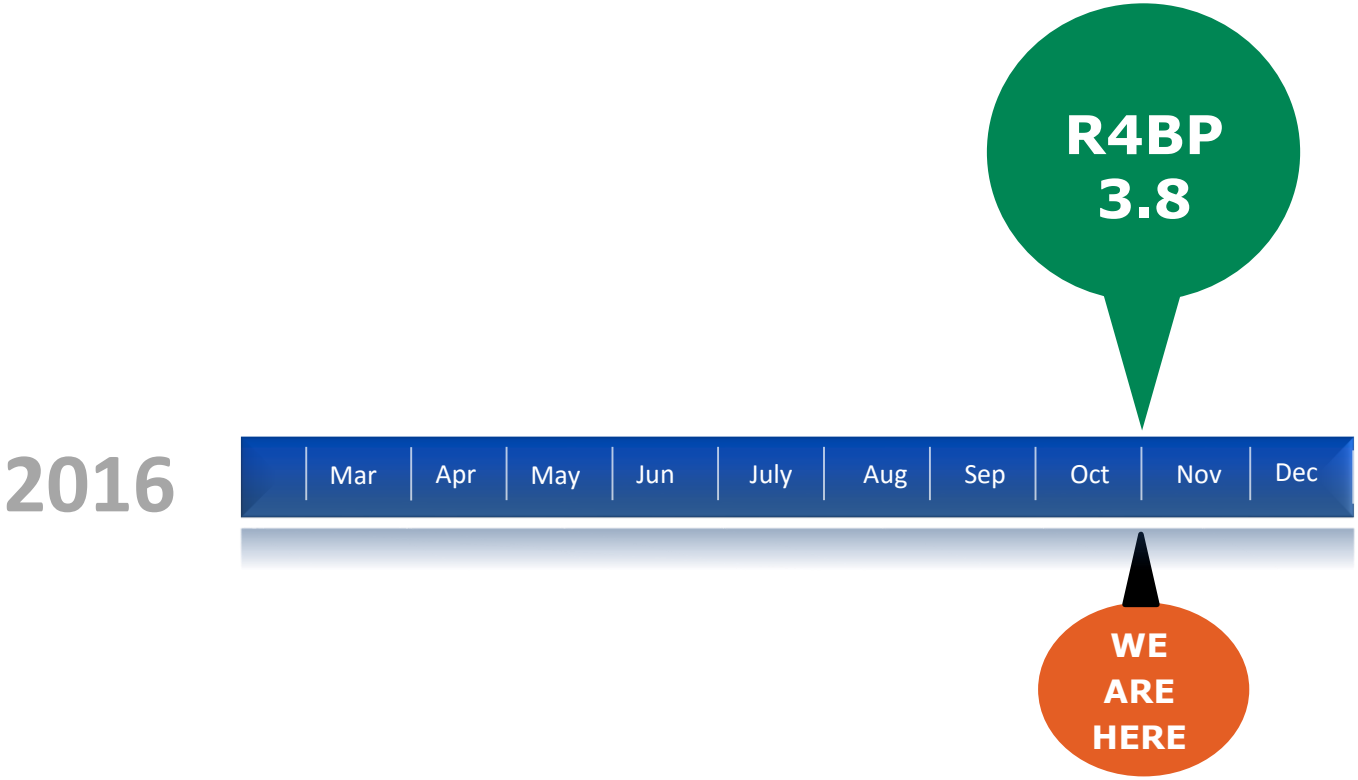
- ECHA prepares and submits an **opinion** to the Commission on the applications for same product for Union authorisations

Guidance

- ECHA prepared a new chapter of the practical guide on same product authorisations
- ECHA published a new web page on same product authorisations

# New features in R4BP 3

# New version of R4BP 3



# Same biocidal product authorisation

- National authorisation based on Union authorisation for same product (NA-BBX)

- Union, national and simplified authorisation for same product from family to reduced family or single product (case types UA, NA, SA-BBX)

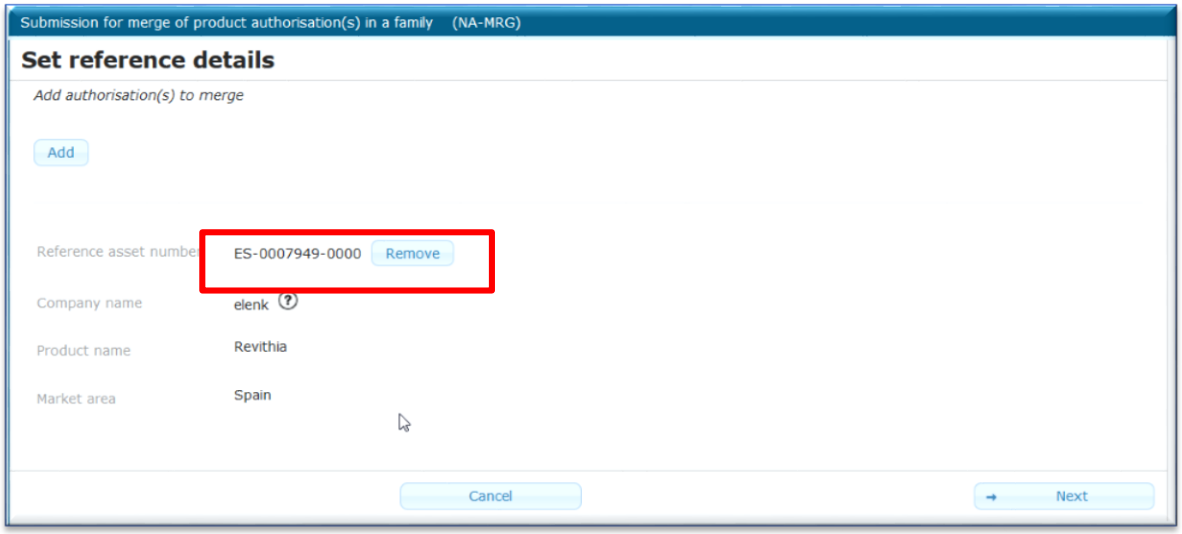
# Modify your Union authorisation

NEW

| Description | Case type | Regulation reference |
|---|---|---|
| Amendment of Union Authorisation | UA-AAT | Article 48 BPR |
| Cancellation of Union Authorisation | UA-CCL | Article 48 BPR |
| Union Authorisation administrative change on request (except asset transfer) | UA-ADC | Article 49, 50 and Article 10, 13 Change Regulation |
| Transfer of an Union Authorisation | UA-TRS | Annex / Title 1 / Section 1 Change Regulation |
| Union authorisation minor change on request | UA-MIC | Article 49, 50 and Article 11, 13 Change Regulation |
| Union Authorisation major change on request | UA-MAC | Article 49, 50 and Article 12, 13 Change Regulation |
| Union Authorisation of the same biocidal product (authorised) | UA-BBS | Article 17 (7) and Article 2, 4, 6 SBP Regulation |
| Notification of product in product family for Union Authorisation | UA-NPF | Article 17(6) BPR |

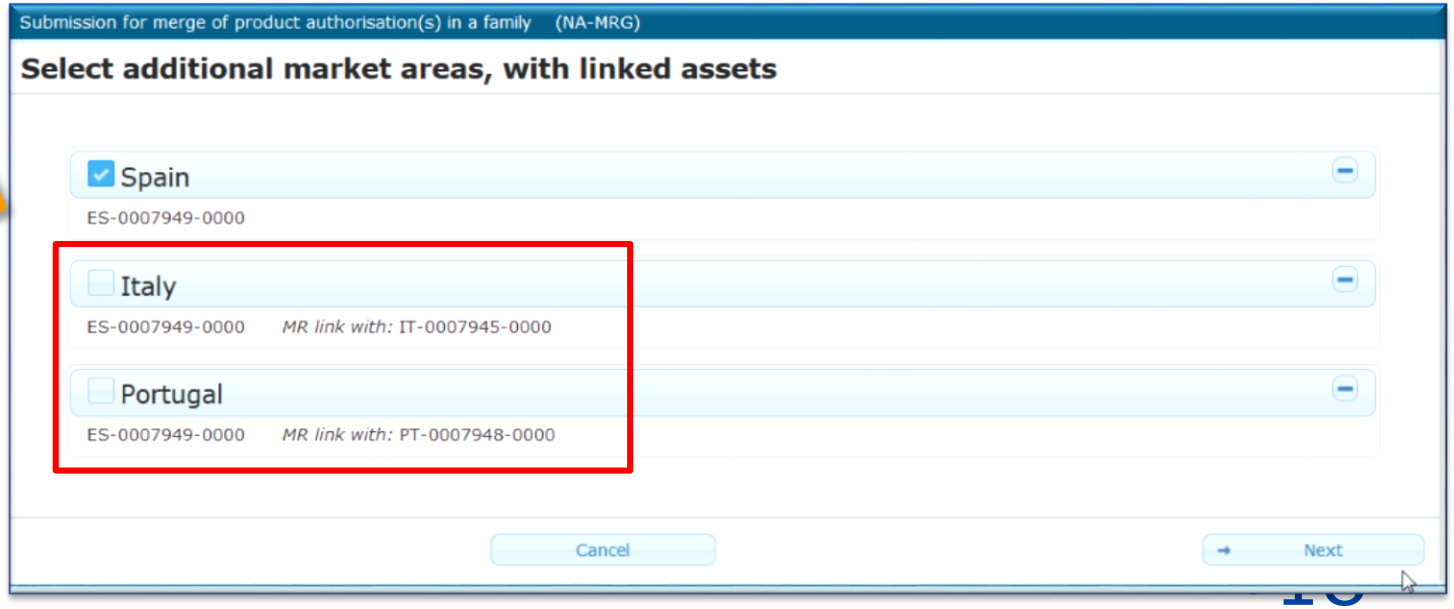
# Single product notification

# Upgraded "Merge" case type

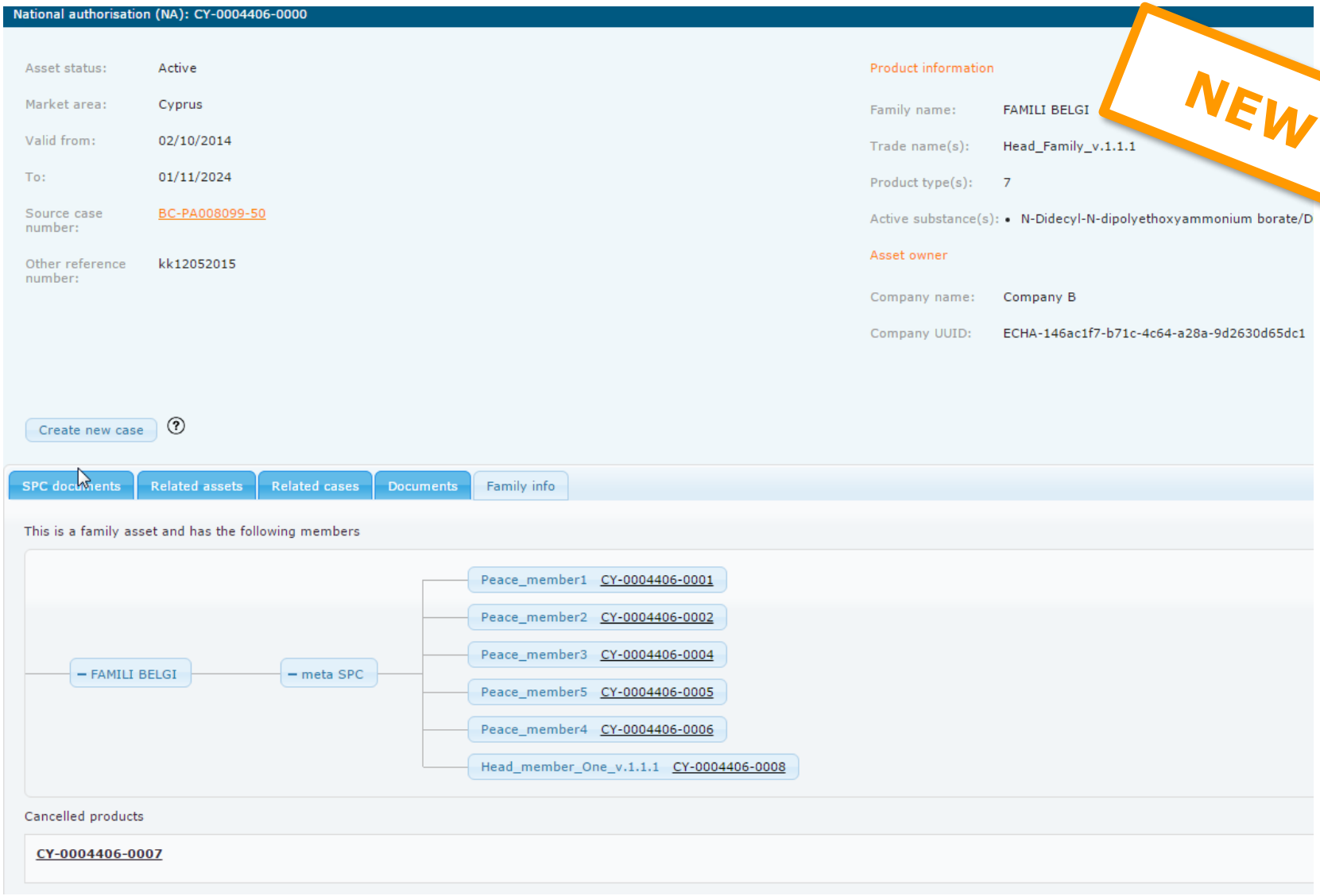



- Select single national authorisation assets that relate to the same market area
- Select multiple national authorisation assets that have a mutual recognition relation with the defined reference assets

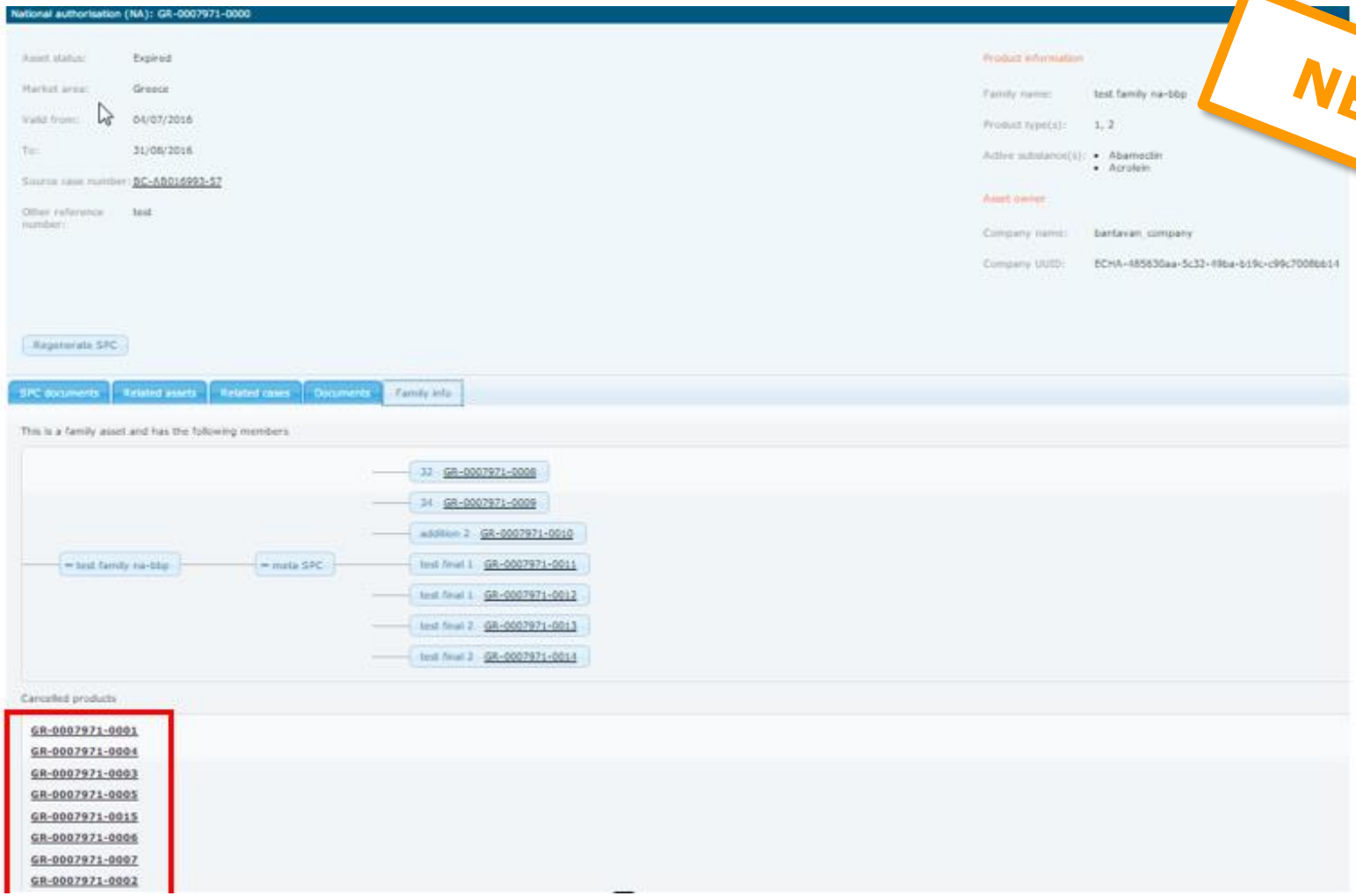
NEW



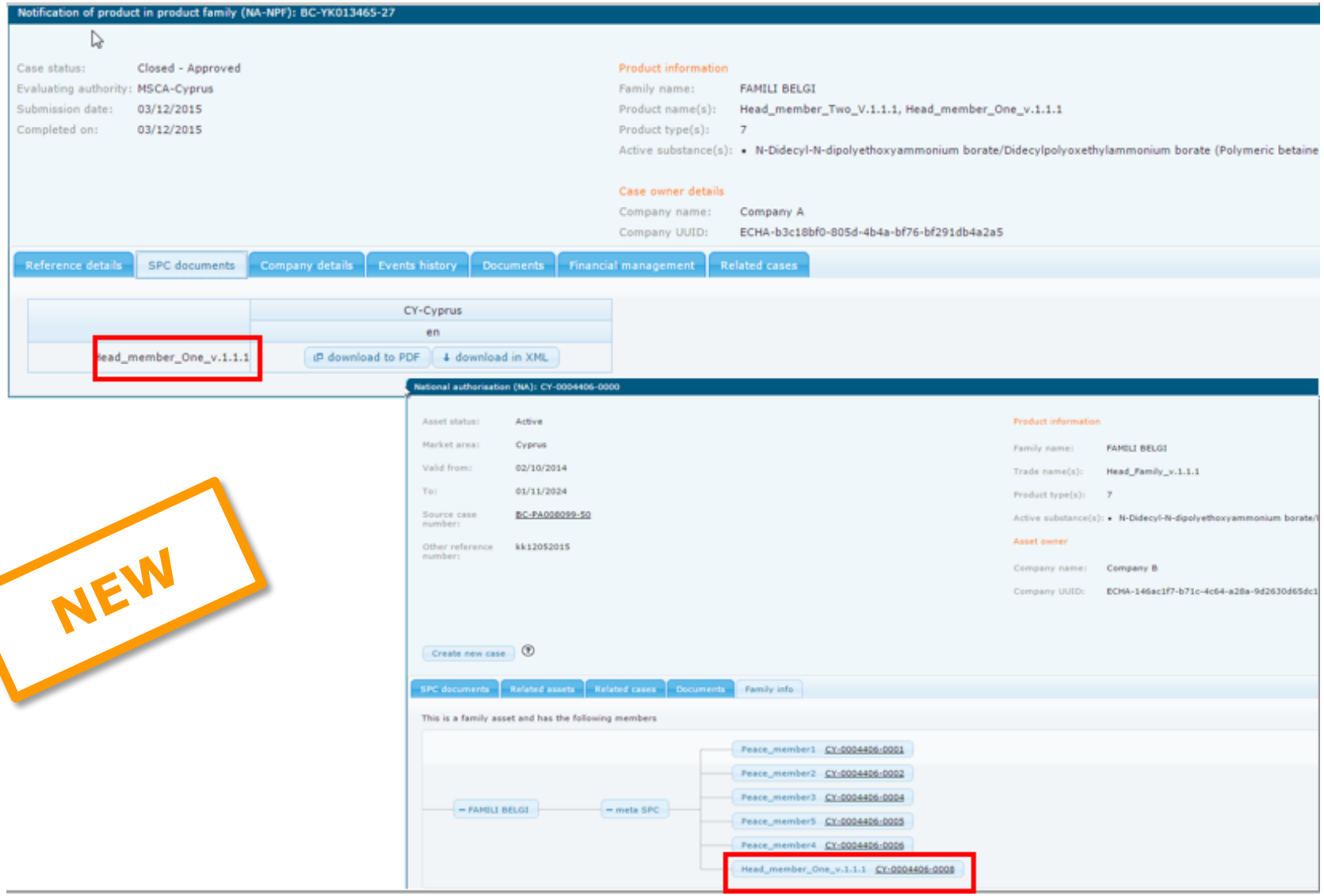
# Enhanced family structure views



# Cancelled members



# Notification of product family (NPF)




NEW

# 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
      - Product family
      - Same biocidal products 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

The authorisation holder can apply for the renewal of an authorisation to the Member State competent authority (MSCA) who granted the authorisation. In case of mutual recognition authorisation, the application for renewal should be submitted to the reference MSCA and all MSCAs concerned.

### Union authorisation

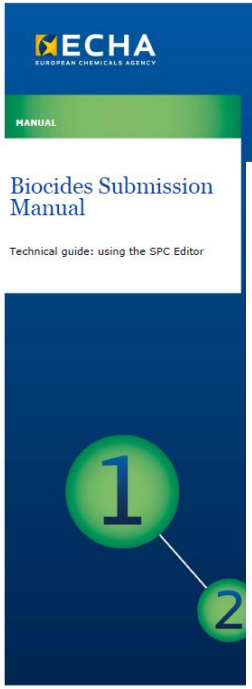
The Biocidal Products Regulation introduces a new alternative for companies that wish to apply for an EU-wide authorisation in one go.

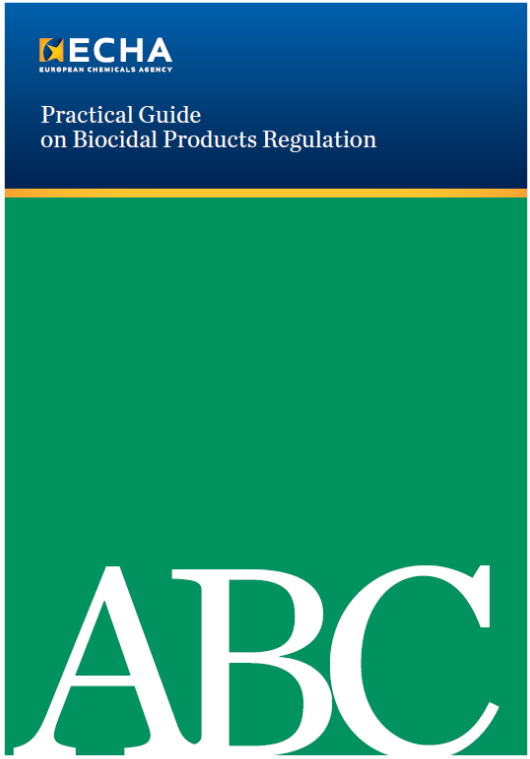
### Simplified authorisation

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.



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