

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

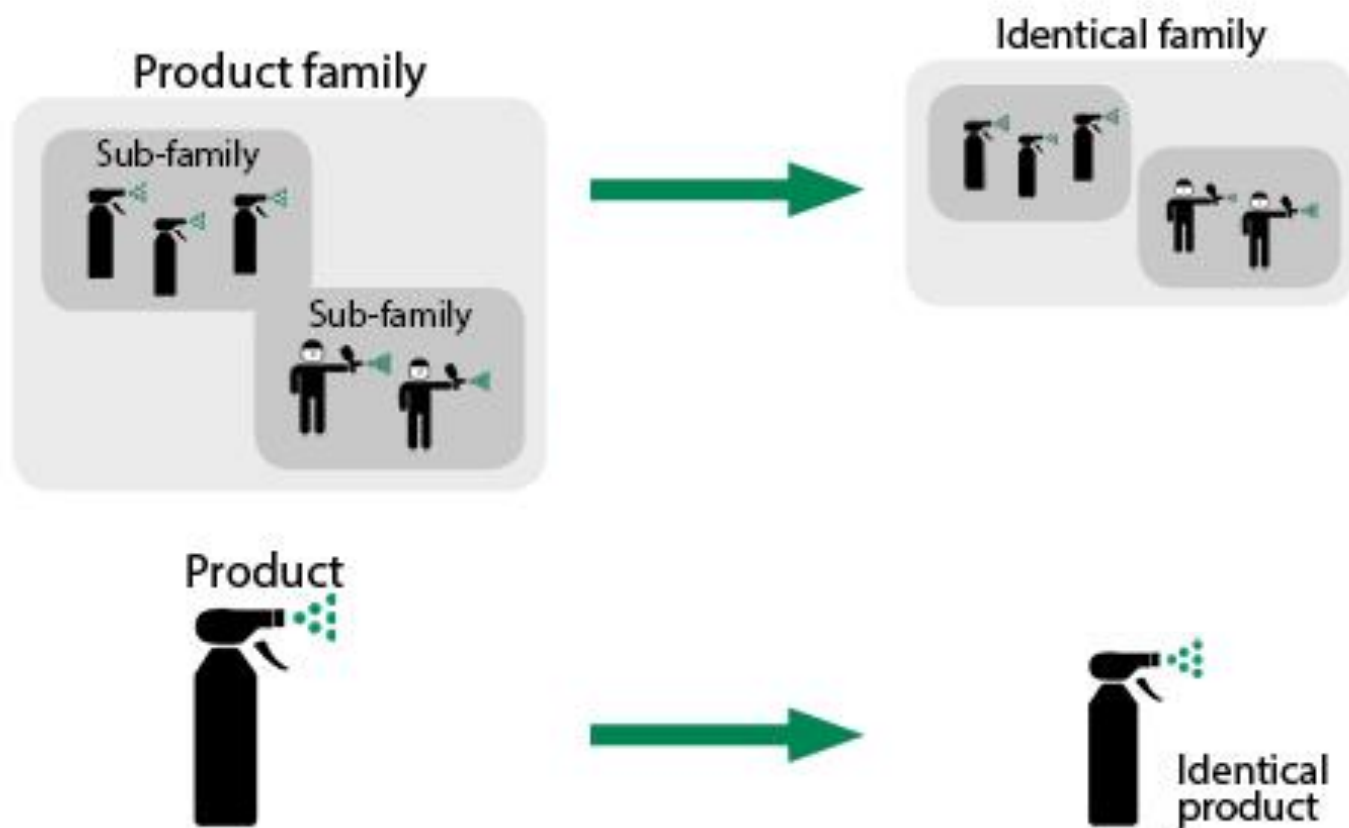
...is the subject of an application for such an authorisation (**pending**)

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

2016



**R4BP
3.8**

**WE
ARE
HERE**

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

NEW

SN-NOT

Simplified authorisation (SA): EU-0007593-0001

Asset status: Active

Market area: European Union

Valid from: 25/05/2016

To: 25/05/2026

Source case number: [BC-AK014854-44](#)

Other reference number: -

Member of an SA family asset

Product information

Product name: Zaino Z-16

Trade name(s): Z-16 Grande Finale

Product type(s): 9

Active substance(s):

- alphachloralose

meta SPC identifier: meta SPC

Suffix of meta SPC: 1-1

Asset owner

Company name: Company A

Company UUID: ECHA-b3c18bf0-805d-4b4a-bf76-bf291db4a2a5

Create new case ?

SN-NOT - Notification for placing on the market

[SPC documents](#) [Designation / nomination](#) [Related assets](#) [Related cases](#) [Documents](#) [Family info](#)

EU-European Union

en

Zaino Z-16

[download to PDF](#) [download in XML](#)

Notify only a member in a specific market area.

Upgraded “Merge” case type

Submission for merge of product authorisation(s) in a family (NA-MRG)

Set reference details

Add authorisation(s) to merge

Reference asset number: **ES-0007949-0000**

Company name: elenk ?

Product name: Revithia

Market area: Spain

- 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

Submission for merge of product authorisation(s) in a family (NA-MRG)

Select additional market areas, with linked assets

☒ Spain
ES-0007949-0000

☐ Italy
ES-0007949-0000 MR link with: IT-0007945-0000

☐ Portugal
ES-0007949-0000 MR link with: PT-0007948-0000

Enhanced family structure views

National authorisation (NA): CY-0004406-0000

Asset status: Active
Market area: Cyprus
Valid from: 02/10/2014
To: 01/11/2024
Source case number: [BC-PA008099-50](#)
Other reference number: kk12052015

Product information

Family name: FAMILI BELGI
Trade name(s): Head_Family_v.1.1.1
Product type(s): 7
Active substance(s): • N-Didecyl-N-dipolyethoxyammonium borate/D

Asset owner

Company name: Company B
Company UUID: ECHA-146ac1f7-b71c-4c64-a28a-9d2630d65dc1

NEW

Create new case



SPC documents

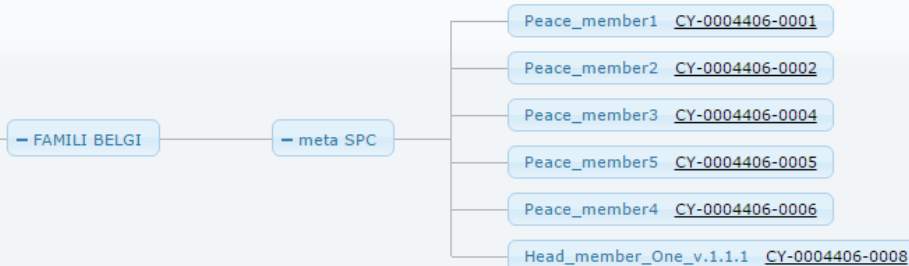
Related assets

Related cases

Documents

Family info

This is a family asset and has the following members



Cancelled products

[CY-0004406-0007](#)

Cancelled members

National authorisation (NA): GR-0007971-0000

Asset status: Expired
Market area: Greece
Valid from: 04/07/2016
To: 31/06/2016
Source case number: [PC-A0016993-52](#)
Other reference number: test

[Regenerate SPC](#)

Product information
Family name: test family na-bbp
Product type(s): 1, 2
Active substance(s):

- Abamectin
- Acrolein

Asset owner
Company name: barfavan company
Company UUID: ECHA-185830aa-5c32-49ba-b19c-c99c70086614

[SPC documents](#) [Related assets](#) [Related cases](#) [Documents](#) [Family info](#)

This is a family asset and has the following members

test family na-bbp → meta SPC

- 32 - GR-0007971-0008
- 34 - GR-0007971-0009
- addition 2 - GR-0007971-0010
- test final 1 - GR-0007971-0011
- test final 1 - GR-0007971-0012
- test final 2 - GR-0007971-0013
- test final 2 - GR-0007971-0014

Cancelled products

- [GR-0007971-0001](#)
- [GR-0007971-0004](#)
- [GR-0007971-0003](#)
- [GR-0007971-0005](#)
- [GR-0007971-0015](#)
- [GR-0007971-0006](#)
- [GR-0007971-0007](#)
- [GR-0007971-0002](#)

NEW

Notification of product family (NPF)

Notification of product in product family (NA-NPF): BC-YK013465-27

Case status: Closed - Approved
Evaluating authority: MSCA-Cyprus
Submission date: 03/12/2015
Completed on: 03/12/2015

Product information
Family name: FAMILI BELGI
Product name(s): Head_member_Two_V.1.1.1.1, Head_member_One_v.1.1.1
Product type(s): 7
Active substance(s): • N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine)

Case owner details
Company name: Company A
Company UUID: ECHA-b3c18bf0-805d-4b4a-bf76-bf291db4a2a5

Reference details | SPC documents | Company details | Events history | Documents | Financial management | Related cases

CY-Cyprus
en
Head_member_One_v.1.1.1
iP download to PDF | download in XML

National authorisation (NA): CY-0004406-0000

Asset status: Active
Market area: Cyprus
Valid from: 02/10/2014
To: 01/11/2024
Source case number: BC-PA036099-50
Other reference number: kk12052015

Product information
Family name: FAMILI BELGI
Trade name(s): Head_Family_v.1.1.1
Product type(s): 7
Active substance(s): • N-Didecyl-N-dipolyethoxyammonium borate/Didecylpolyoxethylammonium borate (Polymeric betaine)

Asset owner
Company name: Company B
Company UUID: ECHA-146ac1f7-b71c-4c64-a28a-9d2630d65dc1

Create new case ⓘ

SPC documents | Related assets | Related cases | Documents | Family info

This is a family asset and has the following members

— FAMILI BELGI — meta SPC

- Peace_member1 CY-0004406-0001
- Peace_member2 CY-0004406-0002
- Peace_member3 CY-0004406-0004
- Peace_member5 CY-0004406-0005
- Peace_member6 CY-0004406-0006
- Head_member_One_v.1.1.1 CY-0004406-0008

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 product 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.

ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

Biocides Submission Manual

Technical guide: using the SPC Editor

1

2

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Practical Guide
on Biocidal Products Regulation

ABC

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