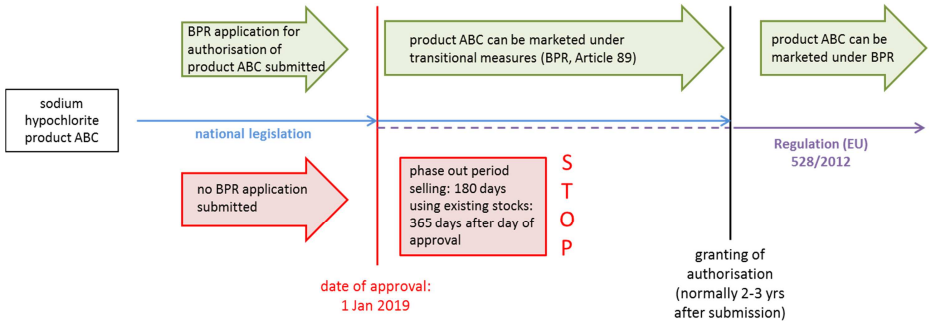
Information on Authorisation and Marketability of Sodium Hypochlorite Biocidal Products

Background

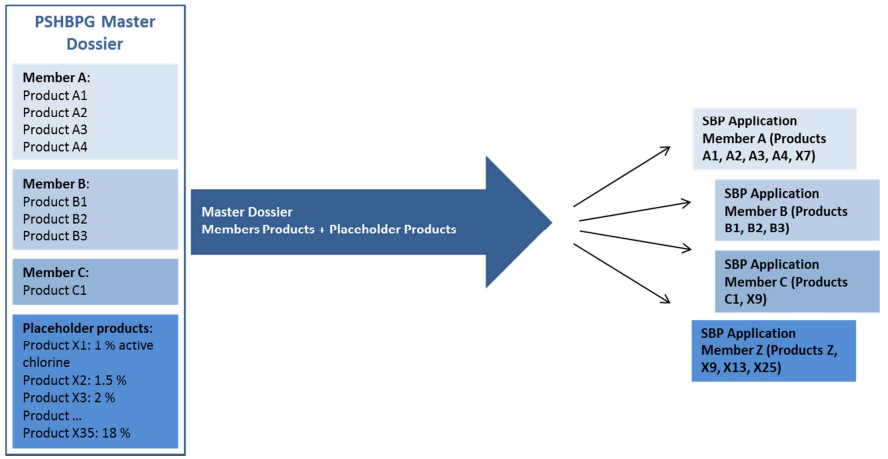
The Biocidal Product Regulation (EU) 528/2012 (BPR) regulates the conditions for making available on the market and use of Biocidal Products in the European Union.
The BPR foresees a two-step procedure, authorising first the biocidal active substance and subsequently Biocidal Products containing this active substance.
An active substance dossier for sodium hypochlorite has been prepared in earlier years by manufacturers who joined efforts in the EuroChlor Biocides Registration Group.
The active substance "active chlorine released from sodium hypochlorite" has been approved for being used as disinfectant in product types (PT) 1, 2, 3, 4 and 5 by Commission Implementing Regulation (EU) 2017/1273 of July 2017. The official **date of approval is 1st January 2019**.
By this date, applications for authorisation of Biocidal Products based on sodium hypochlorite have to be submitted to authorities in order to keep existing Biocidal Products on the market until final authorisation is granted.
A schematic overview is provided below.



Pure Sodium Hypochlorite Biocidal Product Group

The Pure Sodium Hypochlorite Biocidal Product Group (PSHBPG) is a consortium whose Members intend to apply for a Union Authorisation of a Biocidal Product Family (BPF) of pure sodium hypochlorite products in PTs 1, 2, 3, 4 and 5.
This BPF will cover all products and relevant uses of the Members of the consortium. Each Member will subsequently apply for Same Biocidal Product (SBP) authorisation of its own products before the date of approval (1st January 2019).
Besides the Biocidal Products nominated by the Members of the consortium, the consortium pre-defined placeholder products in a top-down approach, covering the concentration range from 1 to 18 % (w/w) active chlorine in 0.5 % steps (see scheme below). Each Member and its Customers can make reference to these pre-defined placeholder products.

Although the consortium Members are mainly active substance producers they have an intrinsic interest in supporting their Customers with their Biocidal Product authorisations. The options for Customers are detailed below.
Please note that only sodium hypochlorite products containing no further co-formulants can be included in the PSHBPG BPF.
The consortium is still open to new Members (two rounds of admission in Mar/Apr 2018 and Jul/Aug 2018). More information can be found on the consortium website (http://purenaclo-bpg.eu/).
The time line for issuing letters of access to products of the Master Dossier as created by the consortium is yet to be defined. **However, no new products will be included in the Biocidal Product Family after August 2018.**



Options for product authorisation for Customers of PSHBPG Members

There are three different options for Customers of PSHBPG Members to obtain an authorisation for their products, which are further detailed in the following:

1. application for Biocidal Product authorisation with an own dossier
2. private label included in Member's dossier/authorisation
3. same Biocidal Product authorisation

Please note that each PSHBPG Member is free to offer only selected options to its Customers.

Inclusion of pure sodium hypochlorite Biocidal Products in the Master Dossier for either Option 2 or Option 3 will be possible only until 31 August 2018.

Overview of different options for Biocidal Product authorisation		PSHBPG Member A	Option 1: Customer's own Biocidal Product Dossier	Option 2: Private Label included in Member's dossier	Option 3: Same Biocidal Product (SBP) Application		
					case A	case B	case C
party		member A	customer 1	customer 2	customer 3	customer 4	customer 5
product		Product A1	Customer Product(s) X, Y, Z	buys Product A1 from member A, relabels as own Product Z	buys Product A1 from member A, relabels as own Product Z	buys active substance from member A, dilutes to Product XY which is identical to placeholder Product X7 of the Master Dossier	buys active substance from <u>different</u> suppliers[§§] dilutes/formulates own Product XY, which is identical to placeholder Product X7 of the Master Dossier
authorisation holder		member A	customer 1	member	customer 3	customer 4	customer 5
label[§]	• trade name • authorisation number (AN) • authorisation holder (AH)	• Product A1 • own AN • AH: member	• Product X, Y, Z • own AN • AH: customer 1	• Product Z • AN (granted to member's product) • AH: member	• Product Z • own AN • AH: customer 3	• Product XY • own AN • AH: customer 4	• Product XY • own AN • AH: customer 5
responsible during transitional period [##]		member A	customer 1	customer 2	customer 3	customer 4	customer 5
to do & costs		equal share of the costs for preparation of Master Dossier, fees and required LoAs	• filing and submission of Biocidal Product application • study costs • fees • costs for LoAs	• covered by Member's dossier/application • costs to be negotiated with Member	• filing and submission of SBP application • fees • costs for LoAs	• filing and submission of SBP application • fees • costs for LoAs	• filing and submission of SBP application • fees • costs for LoAs
LoA to the active substance dossier[*]		required	required	covered by Member's dossier/application	required	required	required
LoA to the Master Dossier of PSHBPG[**]		required	not required, independent from PSHBPG	covered by Member's dossier/application	required	required	required
LoA to the DBP data[***]		required	required depending on availability of own data	covered by Member's dossier/application	required	required	required
LoA to phys-chem & efficacy data [#]		required	required depending on availability of own data	covered by Member's dossier/application	required	required	required

[§] The information provided here does not reflect the full label requirements. Label requirements are defined in Regulation (EU) 528/2012, Article 69.

[##] After submission of the application for product authorisation by 1. January 2019, Biocidal Products containing sodium hypochlorite and covered by an application can stay on the market under transitional measures (Regulation (EU) 528/2012, Article 89), i.e. national legislation. Each authorisation holder is responsible for keeping his products on the market and to fulfil all (national) requirements, until authorisation under BPR is granted.

[*] Letter of access to the active substance dossier for active chlorine released from sodium hypochlorite in PT 1-5; available from EuroChlor members.

[**] Letter of access to the Master Dossier of PSHBPG available from PSHBPG consortium. Terms and conditions are to be decided by PSHBPG.

[***] Letter of access to the data on disinfection by-products generated by the DBP Consortium managed by Arrow Regulatory. Terms and conditions are to be negotiated between each Member and Customer and/or Customer and Arrow Regulatory.

[#] Terms and conditions of data access yet to be decided.

[§§] The active substance (reference source or technically equivalent) purchased from different suppliers can be stored in one storage tank. Please refer also to example 3 below, and to the FECC document on Good Practice of Storage Tank Management.

Option 1: Application for Biocidal Product authorisation with an own dossier

Customers of PSHBPG Members can of course file their own dossier for product authorisation supporting their Biocidal Products, independently of their supplier and of PSHBPG. The BPR allows for Union Authorisations, National Authorisations, and National Authorisation with Mutual Recognition in different EU Member States of interest.

Biocidal Product dossiers must fulfil certain information requirements as detailed in BPR Article 20, and BPR, Annex III, e.g. data must be provided on physico-chemical parameters of products, on the efficacy for the intended uses, and the risk for human and animal health as well as the environment must be assessed. Moreover, a letter of access to the active substance dossier (i.e. for active chlorine released from sodium hypochlorite in the respective product type) is required, which can be purchased from EuroChlor Members.

The authorities of the EU Member States as well as ECHA charge fees for the evaluation of the dossier. Fees are dependent on the type of application (Union or National, BPF or single product) as well as the chosen evaluating competent authority.

Option 1 is independent from and outside the scope of the consortium, therefore no further details are provided in this document.

Option 2: Private label included in Member's dossier

Customers can include their products and trade names in the dossier of the Member from which they buy sodium hypochlorite products. Choosing this option, Customers rely on the Biocidal Product authorisation of their supplier.

Pre-requisite for this option is, that Customers buy a Biocidal Product from a Member of PSHBPG, and only re-package and/or re-label for re-selling under a different trade name. The product must be identical to the Member's product in terms of composition, efficacy, and intended uses (1:1 relation between supplier's product and Customer's Product). Moreover, the relevant reference product of the PSHBPG Member must of course be included in the Master Dossier of the PSHBPG.

No additional costs for dossier preparation or the application for Biocidal Product authorisation will arise for the Customers when they chose this option, and no additional effort has to be taken.

However, the Member will be the future authorisation holder of this product once authorisation is granted (with all rights and obligations). Thus, after authorisation is granted, the name of the Member – being the authorisation holder - must be indicated on the label of the Customer's Biocidal Product as authorisation holder. Customers depend on the Member with respect to possible changes of the Biocidal Product or the supply of the Biocidal Product.

Please note that several EU Member States levy annual fees with respect to Biocidal Products made available on their markets (in accordance with BPR, Article 80(2)). Similarly, for Union Authorisations of Biocidal Products annual fees are charged. These fees will be invoiced to the authorisation holder, i.e. the PSHBPG Member. The handling of these fees has to be negotiated between the PSHBPG Member and its Customer.

The terms and conditions as well as costs for inclusion as private label product into the Master Dossier have to be negotiated between PSHBPG Member and Customer.

Option 3: Same Biocidal Product Authorisation

Customers of Members of PSHBPG can apply for their own Same Biocidal Product (SBP) Authorisation. Fees depend on the chosen evaluating EU Member State, and the authorisation applied for (Union or National, BPF or single product). Customers will have their own product authorisation, independent from the PSHBPG Member.

Again, the Biocidal Product they refer to must be included in the Master Dossier: this can either be a product nominated for the BPF by the Member, or a placeholder product as detailed in the top-down approach. Please note that according to the SBP Regulation (EU) 414/2013, a SBP can differ from the reference product only by changes which are categorized as administrative changes as detailed in Regulation (EU) 354/2013 (e.g. product name, authorisation holder, or manufacturer of the product).

Customers can buy a letter of access to this product in the Master Dossier from the consortium, not from the Member. However, the Member of PSHBPG needs to confirm the business relationship to the Customer; the terms and conditions need to be negotiated between each Member and its Customer. The further terms and conditions for the LoAs to the Master Dossier need yet to be decided within PSHBPG.

In addition, Customers will require in any case a LoA to the active substance dossier for sodium hypochlorite. This LoA is available from Eurochlor members.

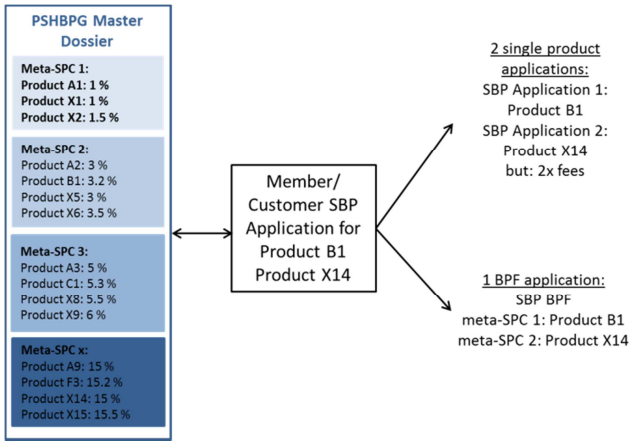
As the PSHBPG will potentially buy testing data from another consortium, data access to this data might be required as well. Moreover, PSHBPG intends to become a member of the Disinfection By-Products Consortium managed by Arrow Regulatory and to use the data generated there in the Master Dossier. The details and conditions for access for Costumers to this data need yet to be clarified, but potentially additional costs will arise.

Customers are responsible for preparation and submission of their own application for Same Biocidal Product Authorisation; the SPC (Summary of Product Characteristics document) – an excerpt of the Master-SPC – will be prepared by the Technical Consultant of PSHBPG together with the required supporting document for reasons of confidentiality.

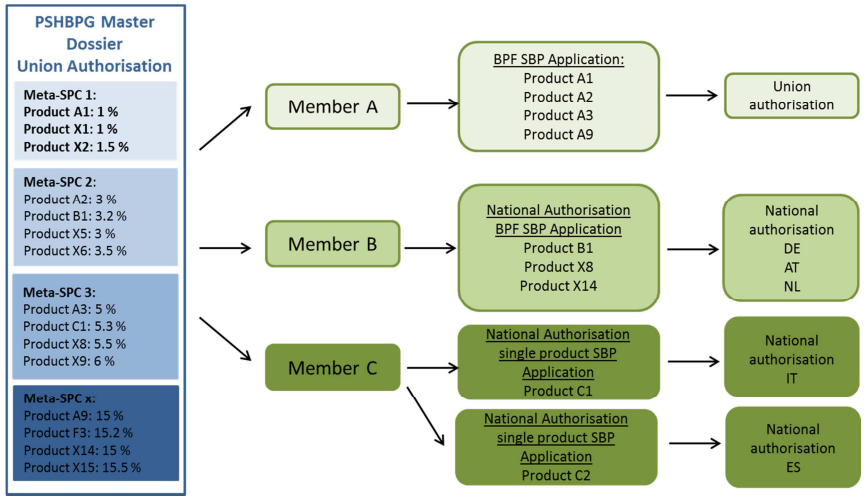
Please note that the SPC document– listing amongst others the Biocidal Product manufacturer(s) and active substance supplier(s) - will be published by ECHA/Member States once product authorisation is granted for SBPs as well as for other Biocidal Product authorisations.

Different possibilities of Same Biocidal Product applications

There are different possibilities to apply for the authorization of a Same Biocidal Product (SBP). You can either apply for a single SBP, or for a Same Biocidal Product Family. In the latter case, you could e.g. make reference to a subset of the Master Dossier BPF picking the products of interest.



Further, a SBP application (either for a single product or for a BPF) can be filed for a single EU Member State, for several EU Member States or for the complete EU (Union Authorisation). Examples are depicted in the following scheme:



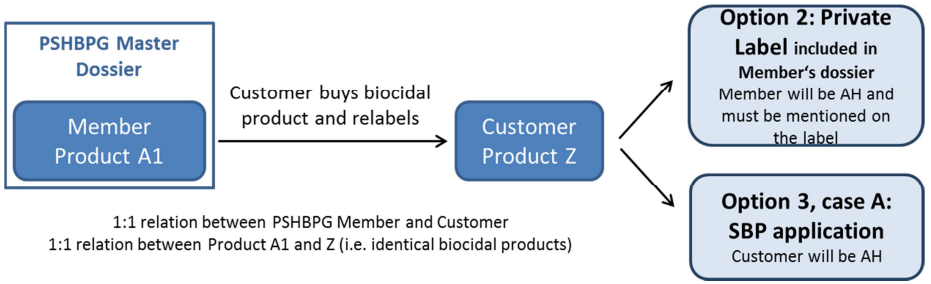
Examples for Customer-Member-Relationship and options for product authorisation

Example 1: Customer buys Biocidal Product A1 and re-labels as Product Z

A Customer buys a Biocidal Product (Product A1) from a supplier who is a PSHBPG Member. The customer re-labels this product and markets it under his own trade name as Customer Product Z, but does not change the formulation, does not dilute the product and has no additional uses, user categories or efficacy claims.

This Customer can either go with Option 2, i.e. include his product as trade name of the Member's Product A1 in the PSHBPG Master Dossier ("private label"). The Customer Product Z will then be covered by the Member's Application for authorisation; the PSHBPG Member will be the authorisation holder after authorisation is granted, and the Member has thus to be named on the label of Product Z as authorisation holder.

The Customer can also choose Option 3 (see also Case A in the overview table above), and apply for a Same Biocidal Product authorisation for his product. In this way, the Customer will have his own Biocidal Product authorisation in the end.

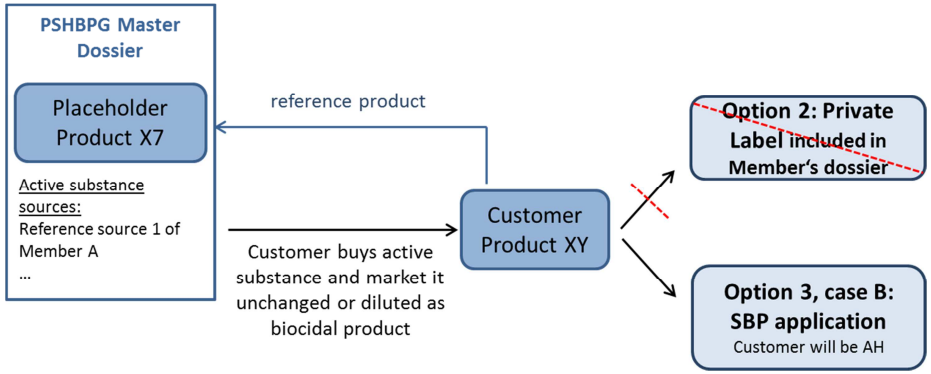


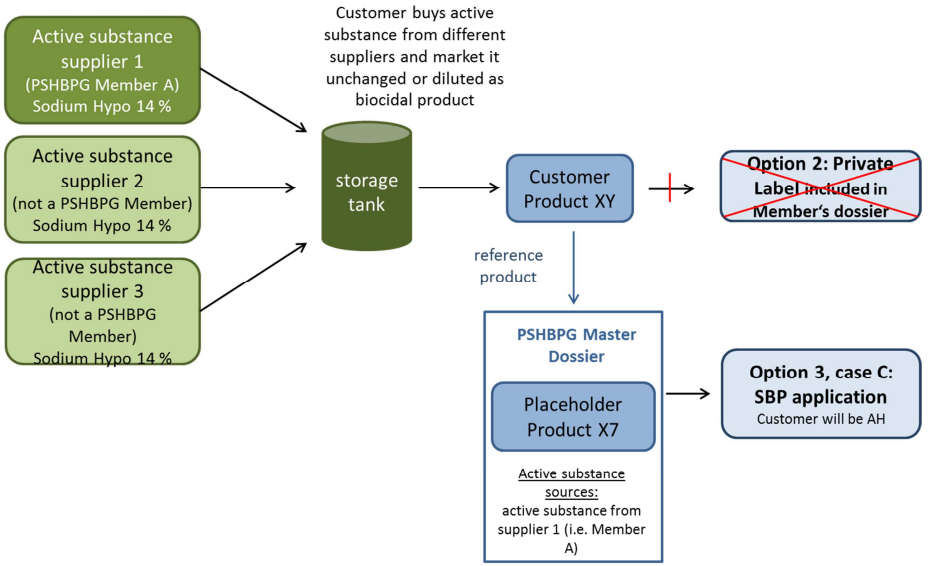
Example 2: Customer buys active substance from PSHBPG Member and dilutes it to Product XY

A Customer buys sodium hypochlorite as biocidal active substance (e.g. "Sodium hypochlorite 14 %") from one supplier who is a PSHBPG Member. The Customer markets this active substance without further changes as a Biocidal Product, or he markets a dilution of the active substance as Biocidal Product under the trade name Product XY.

If Product XY corresponds to one of the placeholder products in the PSHBPG Master Dossier, the Customer can make reference to this placeholder product, and apply for SBP authorisation (see Option 3, Case B in the overview table above).

NB: Option 2 (Private Label included in Member's dossier) would be an option only if the supplier (i.e. the PSHBPG Member) is willing to take over the responsibility for Product XY and to include it in the Member's SBP application as well as in the Master Dossier.





Example 3: Customer buys active substance from different suppliers and dilutes it to Product XY

A Customer buys sodium hypochlorite as biocidal active substance (e.g. "Sodium hypochlorite 14 %") from different suppliers. At least one of these suppliers is a Member of PSHBPG. The Customer markets this active substance without further changes as a Biocidal Product, or he markets a dilution of the active substance as Biocidal Product under the trade name Product XY.
If Product XY corresponds to one of the placeholder products in the PSHBPG Master Dossier, the Customer can make reference to this placeholder product, and apply for SBP authorisation (see Option 3, Case C in the overview table above). The Customer needs to list all his active substance sources in the application for SBP authorisation. Of course the active substance sources must all be either reference sources or technically equivalent, and listed on the Art. 95 list. For more information on the use of active substances from different suppliers, you may also refer to the FECC document "Good practice guidance storage tank management for biocidal active substances".

Abbreviations

AS	Active substance as defined by the BPR, Article 3(c)
BP	Biocidal Product as defined by the BPR, Article 3(a)
BPF	Biocidal Product Family as defined by the BPR, Article 3(s)
BPR	Biocidal Product Regulation (EU) 528/2012
DBP	Disinfection By-Product
LoA	Letter of access
PSHBPG	Pure Sodium Hypochlorite Biocidal Product Group
PT	Product type as defined in Annex V of the BPR
SBP	Same Biocidal Product in accordance with Regulation (EU) 414/2013
SPC	Summary of Product Characteristics, a document required for submission of Biocidal Product applications to the authorities