



ReachCentrum Biocide Newsletter Issue 1, February 2015

Dear reader,

We are pleased to introduce to you to the first edition of *Biocide focus*, the ReachCentrum Newsletter dedicated to Biocidal Product Family (BPF) Consortia.

Biocide focus addresses news about general regulatory issues related to the Biocide world. A special section is dedicated to further steps inside BPF consortia ReachCentrum is launching, to keep you up-to-date with the latest news. A further section is also dedicated to upcoming Biocides events, where you will be able to meet your ReachCentrum referent, and information about tailored Biocide trainings ReachCentrum is organising in Brussels.

Following a first kick-off meeting in September 18th 2014, many companies have expressed their interest and signed the agreement for pre-Consortium for Sodium Hypochlorite as active substance. ReachCentrum and Arche team is working on details regarding the consortium and its set-up.

A kick-off meeting for setting up Biocides Consortia for Product Authorisation for several active substances will be held in Brussels on February 20th 2015. Involved substances are listed inside *Biocide focus*.

The ReachCentrum team

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> Latest from our blog:

[REACH us everywhere](#)
ECHA publishes Guidance on active substance

> Latest from our tweet account:

[@ReachCentrum](#)
Support to prepare applications for #REACH #Authorisation: @EU_ECHA releases preconfigured #IUCLID5 <http://is.gd/tVyPa7>

Eye on consortium

Pre-Consortium launch



The first Biocidal Product Family (BPF) pre-Consortium for Sodium Hypochlorite as an active substance has been set-up by ReachCentrum and Arche (as Technical Service Provider) in November 2014. As of today, 34 companies have joined the BPF pre-Consortium to be compliant with the Biocidal Products Regulation. Among pre-Consortium members, EuroChlor companies as well as other small and medium enterprises from all around Europe.

ReachCentrum, as Secretariat of the pre-Consortium, has collected the questionnaires containing information on the uses, Product Types (PTs) of interest and composition of formulations from companies. ARCHE will group companies with similar formulations and uses under the same Product Family in order to create Biocidal Product Family dossier(s), to be submitted to the Authorities for Authorisation requirements. ReachCentrum is working on the organisation and structure of pre-Consortium/Consortium bodies: Technical Committee, Steering Committee and Secretariat. Also, it is performing its tasks regarding the creation of a model for data and cost sharing. This will then be presented to Consortium members for revision and approval.

ReachCentrum is also working on Consortium members' costs exercise, taking into account 34 companies, including dossier preparation and management costs, to be shared by members both for the Union Authorisation and National Authorisation. This action follows the new "Report on the fees payable to Member States Competent Authorities pursuant to Article 80(2) of the Biocidal Products

Regulation" published following November 14th meeting of the Competent Authorities.

> [Report on fees CA-Nov.14-Doc.7.2](#)

Upcoming

In the coming months a new **Tool for fees calculation** for Union Authorisation and National Authorisation applications will be launched on the ReachCentrum website www.reachcentrum.eu. Announcements will be made as soon as the tool is published.

Following a 2014 call for interest, ReachCentrum, in collaboration with Arche, is leading a **kick-off meeting for setting up Biocides Consortia** for Product Authorisation for the following active substances:

- IPA - Isopropanol (Propan-2-ol)
- Permethrin
- Hydrogen peroxide
- Peracetic acid
- Chlorine
- Hydrogen Chloride
- Calcium hypochlorite
- Benzalkonium Chloride
- Didecyl dimethyl ammonium chloride (DDAC)

The kick-off meeting will be held on February 20th, 2015 at Cefic in Avenue E. Van Nieuwenhuysse 4, B-1160 Brussels.

The link for registration is > <https://www.regonline.co.uk/builder/site/Default.aspx?EventID=1671726>

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Regulatory corner

Implementing the new concept of Biocidal Product Families

Final document on the new concept of Biocidal Product Family

European Commission has published a final document on the new concept of Biocidal Product Families. The document is structured in five sections addressing:

- Understanding of the elements involved in the new Biocidal Product Family concept,
- Preparation of the application for authorisation of a Biocidal Product Family,
- Evaluation of the Biocidal Product Family application by CAs,
- Content of a Biocidal Product Family authorisation, and
- Post-Authorisation notification of new products.

The proposal provides clarity on the authorities' view of the interpretation relating to the new definition of a Biocidal Product Family. In addition to having different compositions, it is intended for different uses, including different user categories, and also varying risk or efficacy levels. It is even foreseen by the proposal that products within a Biocidal Product Family may belong to different product types (or different combinations of PTs).

The concept of "meta SPC" is further illustrated, stating that where the assessment of the maximum risk and minimum level of efficacy for the entire BPF is not possible, that assessment may be done at meta SPC level.

[> Implementing the new concept of biocidal product families](#)

Report on the fees payable to the Members States Competent Authorities pursuant to Article 80(2) of the Biocidal Product Regulation

The European Commission, with the Report on the fees payable to Member States Competent Authorities pursuant to Article 80(2) of the Biocidal Product Regulation" (CA-Nov.14-Doc.7.2), has issued a guidance document containing recommendation for Member States' fees structures and procedures containing the amount of fees payable to the Competent Authorities. Objective of the guidance is to review the implementation of the Article 80(2) of the

BPR based on the fee-related legislative provisions currently in force in Member States.

[> Report on fees CA-Nov.14-Doc.7.2](#)

In situ generated active substances

European Commission has established that approval of active substances in situ generated ([> document](#)) will be defined by reference to the precursors, supported in the dossier under evaluation, and to the substance generated and should not refer to the precursors used to generate it.

Authorities also endorsed guidance documents on:

- [Further guidance on the application of the substitution criteria of Article 10,](#)
- [Procedures related to the examination of the exclusion criteria and conditions for derogation,](#)
- [A proposed human health assessment scheme for the authorisation of biocidal products, containing substances of concern,](#)
- [The application of the provisions of Article 56 on research and development,](#)
- [Data sharing, letter of access and Consortium: practical guidance for SMEs, and](#)
- [User Guide Consortia](#)

ReachCentrum is supporting companies making available biocidal products on the market to ensure that either the "substance supplier" or "product supplier" is included in the list published by ECHA under Article 95(1) of BPR, for which the deadline is September 1st, 2015. Article 95 List requires submission of a dossier to the European Chemicals Agency and/or sharing of appropriate dossier data (via a Letter of Access).

As a follow up from the call for expression of interest launched in December 2014 on request of the interested suppliers (EuSalt) of NaCl, and in order to support interested companies in setting up a Consortium, ReachCentrum and Arche attended a kick-off meeting organised by EuSalt and other interested parties on February 2nd, 2015.

ReachCentrum and Arche will also join on February 24th a meeting organized by Aqualution Systems Ltd., Puricore Europe Ltd. and EuroChlor on data sharing via Letter of Access. Representatives from European Commission will be present to explain the guideline on how negotiations should be conducted.



Upcoming training

> **IUCLID5 training for Biocides - Brussels, February 26-27, 2015 - [read more](#)**

ReachCentrum and its training partner Arche are offering a two -day IUCLID 5 training course for biocide dossier submission. The course mirrors the Biocidal Products Regulation (BPR) and explains the workflow for preparing biocidal active substances and products.

The course unfolds details of the entire process for biocidal submission, beginning with creating an account, setting up a legal entity, generating and submitting a dossier. [Registration](#)

> **Risk Assessment for Biocides - Brussels, March 11-13, 2015 - [read more](#)**

ReachCentrum and Arche are offering a Risk Assessment for Biocides training course examining the concepts and tools used to calculate risks. The course covers worker and environment assessments, and demonstrates various software tools used to calculate these assessments. Training delivery includes active involvement, sequencing and structuring so that each day is a building block from the previous day, transfer of knowledge by deploying effective learning principles, and team building activities to enhance motivation.

[Registration](#)

Future event

> **3rd Annual European Regulatory Conference on Biocides: A Strategy for Product Authorisation - Brussels, February 3rd, 2015 - [read more](#)**

The conference programme looks at the what, how and when of product authorisations with policy, practical advice and experience delivered from experts and practitioners. At the event, you will have the possibility to meet ReachCentrum Project Managers, and receive our brand new brochure on Biocides service.

> **4th Symposium on Biocidal Products Regulation (BPR) - Brussels, March 17th, 2015 - [read more](#)**

This symposium, organised by Arche, will give you a comprehensive overview of the changes the Biocidal Products Regulation. ReachCentrum, as Arche partner, will attend the event to share with you more information about the Biocidal Product Family topic.

> **ChemicalWatch Biocides Symposium - Ljubljana, May 11-13, 2015 - [read more](#)**

This two day Symposium will focus on BPR examining in depth the various product authorisation processes foreseen within the Regulation and will include presentations on applications for first Union Authorisation together with authorisation of product families. **Leondina Della Pietra, ReachCentrum Project Manager for Biocide Consortia, will deliver a presentation addressing case studies on consortia.**



**Drop a line to
Francesca Furlan at
ffu@reachcentrum.eu to
receive our brand new
brochure on Biocides
service**

Biocide focus is the news sheet of ReachCentrum for Biocidal Product Family Consortia. The news sheet is written in collaboration with Arche. ReachCentrum
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