

Steptoe



Consortia for Biocidal Product Families

A Value Proposition from CEHTRA & Steptoe



January 2019

What Can Companies Gain with a Biocidal Product Family Consortium?

Companies wishing to obtain authorisations for their biocidal products under the Biocidal Products Regulation have the opportunity to work together within a consortium to prepare a joint biocidal product family. This allows members to save time and optimise resources to obtain market access for their products.



Sharing regulatory burden (e.g. data sharing)



Sharing costs (studies, fees)



Sharing and consolidating knowledge and resources



Limits duplication of dossiers



Input on member's products in development BPF



Economies of scale

What Can CEHTRA and Steptoe Offer Potential Biocidal Product Family Consortia?



Steptoe

CEHTRA is a **consultancy company** that was created almost 20 years ago and has grown into a highly respected regulatory compliance consultancy firm with agencies across Europe (France, Belgium, UK, Spain and Germany).

Our **EU team's services** cover: biocides, chemicals (REACH Authorisation), cosmetics, food & packaging, pharmaceuticals, plant protection, medical devices.

Our focus is on scientific and innovative solutions ensuring **regulatory compliance** of chemicals with international obligations. With the **multi-cultural** and **international profiles** of our consultants we not only have high quality technical expertise but also linguistic capacities.

Our consultants provide high quality personalised regulatory services to companies such as yours committed to the safety of their products, at optimized costs.

Our consultants have strong Industry & Competent Authorities knowledge from previous professional experiences.



Steptoe is an **international law firm** focused on regulatory issues and litigation, with over 500 lawyers and other professionals in offices in Beijing, Brussels, Chicago, London, Los Angeles, New York, Phoenix, San Francisco, and Washington.



Our **EU team's work** concerns primarily chemicals regulation, mainly: biocides, REACH, plant protection products, cosmetics and food contact materials. We have been active in all these areas since the respective EU regimes were first proposed and worked at all stages of their implementation.



Our team is **multidisciplinary** and **multi-lingual**: we are lawyers, scientists, and policy advisers who serve clients with an in-depth legal and scientific knowledge of the requirements.



Steptoe has the largest dedicated EU chemical and environment regulatory practice in Brussels, consistently ranked in the top tier for chemicals and environment work by legal directories. *Chambers Europe* recently declared Steptoe's environmental capabilities to be "stellar."



We regularly represent clients before both European and national authorities as well as in litigation before European and national courts.

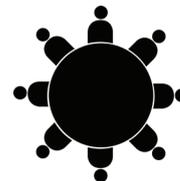
Relevant Combined Experience for Biocidal Product Family Consortia

Together, CEHTRA and Steptoe offer a unique combination of in-depth expertise and understanding of the regulatory and legal requirements to provide seamless support and maximise value for all consortium members.

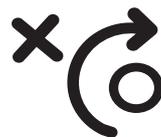
50+ Consortia



We have managed over 50 consortia in the EU and beyond, providing assistance and advice on technical aspects, dossier submission, data sharing, corporate structuring, consortia set-up and management, and advice to consortia members regarding their obligations. We also have financial management, accounting and organizational skills to provide comprehensive support including independent secretariat, trustee etc.



We have been selected to represent Industry in the Working Party for Biocidal products Family with the European Commission and ECHA, actively participating in the discussions on the understanding and practical implementation of this BPR concept.



We have successfully completed and submitted many Biocidal Product Authorisations and Biocidal Products Family dossiers from start to finish without counting the numerous projects for regulatory support, monitoring, outdoor operator exposure studies, expert advice and position papers.



We have a longstanding practice of supporting companies and providing advice on compliance under the EU review programme for biocidal active substances and in their product authorisations. In this regard, we have worked in the biocides sphere with most chemicals companies in the specialty chemicals sector, either as individual clients or as members of trade associations, taskforces or consortia with which we work.

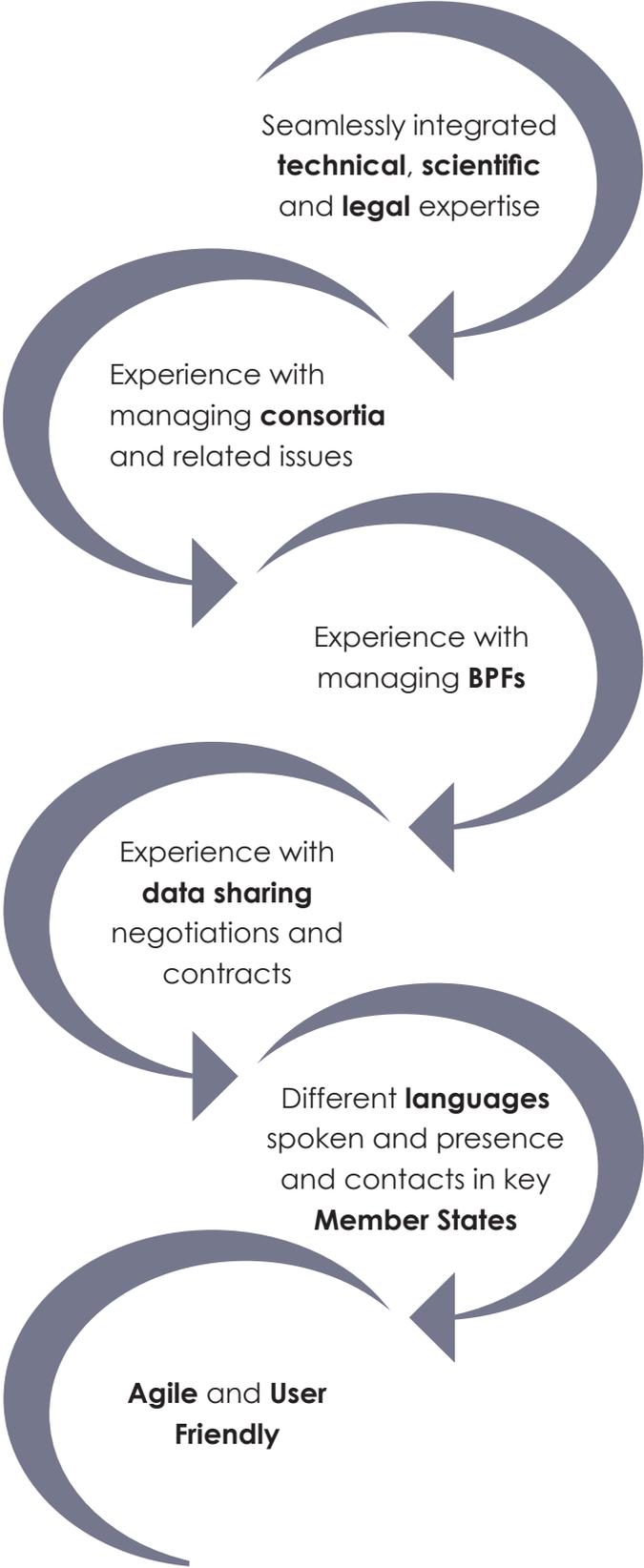


We have extensive experience representing clients in data sharing negotiations. This includes drafting of data sharing agreements between multiple parties forming part of a taskforce or consortium and extensive negotiations on their final terms, the value of the data in issue, all other contractual terms, and the execution of the agreements throughout their operation. This includes establishing principles for data sharing agreements as between a taskforce or consortium and third party non-members of those groups. This also includes representing clients in data sharing disputes and related litigation where necessary.



We also advise on interpretative questions on matters related to cooperation in consortia - including EU antitrust advice - and on related matters of mandatory disclosure of Confidential Business Information (CBI) submitted to regulatory authorities.

CEHTRA-Steptoe Joint Offering for Biocidal Product Family Consortia



How to Contact Us?

For further information or questions, please feel free to reach out to any of our contact persons:

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