EUROPEAN BIOCIDAL PRODUCTS REGULATION APPROVAL OF ECA CONSORTIUM FOR ACTIVE CHLORINE PRODUCTION

DHI as consultant in obtaining approval status as supplier of in-situ generated biocidal active substances

DHI provided assistance to ECA Consortium in their bid to achieve regulation compliance to the European Biocidal Products Regulation (BPR). The ECA Consortium is an international non-profit association dedicated to promote the use of the ECA (Electro Chemical Activation) technology. Member companies within the consortium co-operate in matters concerning ECA applications that are regulated by the BPR. With our knowledge and expertise, we have provided them with consultancy services and advice on how to deal and comply with the regulation requirements.

The active substance dossier includes both active chlorine and sodium chloride and covers the use of substances within products such as disinfectants © iStock / perkmeup

ADDRESSING REGULATION ISSUES

The BPR regulates the placing on the market of all biocidal products including disinfectant products not covered by other regulations such as medical devices, cosmetic products and veterinary medicine. Previously, more traditional disinfectant products that were produced, stored and provided to the end user over the course of time were within the scope of the regulation. However, with the change in regulation since September 2013, the scope of the regulation also includes biocidal products produced or generated from precursor substances that are used on site (in-situ generated biocidal products). The change of scope results in a large number of companies producing in-situ generated biocidal products or placing them on the market. Consequently, they begin to plan their compliance strategy in order to continue their business in the EU. These groups

CLIENT

ECA Consortium

CHALLENGE

- Adhering to complex regulations to acquire compliance from regulating bodies
- Insufficiency of regulatory and practical guidelines
- Deadline for compliance

SOLUTION

DHI functions as regulatory adviser for:

- Performance of data gap analysis
- Preparation of a complete dossier on active substance and precursor

VALUE

- DHI's solution kept the client on the market Non-compliance meant withdrawal of ECA Consortium members' business from the European Union

LOCATION / COUNTRY

Global

of companies are unaccustomed to deal with complex regulations such as that set by the BPR. Companies require additional regulatory and practical guidance from the regulating bodies like the EU Commission or the European Chemicals Agency (ECHA) that is not provided. The situation of in-situ is a moving target, making it difficult for companies to manoeuver in.

DHI SOLUTION TO CHALLENGES

As the regulatory adviser, DHI has facilitated the formation of the ECA Consortium in its inception. As such, we have assisted in the communication between the regulatory bodies (EU Commission and ECHA) and ECA Consortium and member state authorities which has helped the ECA Consortium to be recognised as a stakeholder and to influence the decision process at the EU level.

DHI helped the ECA Consortium navigate the complex regulations with regard to substances generated in-situ for disinfection of drinking water
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In solving the challenges that arose from the change in regulations, DHI has aided the consortium by performing a data gap analysis in order to pinpoint the data and information endpoints that could be covered by publicly available data or those which had to be covered from external sources. This allows the client an overview of the amount of work required in the future which will lead to a more precise cost analysis. In addition, we performed a cost analysis study depicting the costs incurred to authorities, Contract Research Organisations (CROs), data sharing sources, and for seeking legal help and technical work. This enabled us to quantify the foreseeable costs to appeal to other ECA companies.

GETTING ON THE ARTICLE 95 LIST

DHI also arranged and prepared a complete active substance dossier on active chlorine generated from sodium chloride to be submitted to ECHA. The dossier included information on both active chlorine and its precursor chemical, sodium chloride. It contains more than 500 endpoints that would be covered by publicly available data, self-generated data within the ECA Consortium and also external data shared through license agreements. In addition, it contains a thorough exposure and risk assessment that covers the use of representative products within:

- Human hygiene products (PT 1)
- Disinfectants and algaecides not intended for direct application to humans and animals (PT 2)
- Veterinary hygiene products (PT 3)
- Food and feed area (PT 4)
- Drinking water (PT 5)

IN BRIEF

Within a short timespan, DHI assisted 15 companies with:

- Formation of the ECA Consortium
- Communication with European regulatory bodies and EU member state authorities
- Preparation of data gap analysis
- Quantification of a detailed cost analysis study
- Completion of the active substance dossier containing more than 500 endpoints which includes a thorough exposure and risk assessment
- Meeting regulatory deadline

PROJECT VALUE

With the submission of the dossier before the deadline and its subsequent approval by ECHA, all members and associated members of the ECA Consortium are now listed as approved biocidal active substance and product suppliers under Article 95 list of the BPR, which sets the legal basis for placing active substances or products on the market in the EU. The successful listing secured the basis for future business of all members of the ECA Consortium.

CLIENT TESTIMONIAL

> *The ECA Consortium has been very impressed with DHI's expertise and professionalism. Reports and dossier work were delivered on time with a high quality and within very short deadlines. DHI has been the key contributor in getting members of the ECA Consortium listed as approved biocidal active suppliers.*
>
> *Peter Madsen—Chairman—ECA Consortium*

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